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OSTEOPOROSIS

HEARING

BEFORE THE

SUBCOMMITTEE ON AGING

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

REVIEWING THE DIAGNOSIS AND TREATMENT OF OSTEOPOROSIS

JUNE 20, 1985

Printed for the use of the Committee on Labor and Human Resources

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OSTEOPOROSIS

THURSDAY, JUNE 20, 1985

U.S. SENATE,
SUBCOMMITTEE ON AGING,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The subcommittee met, at 9:40 a.m., in room 430, Dirksen Senate Office Building, Senator Charles E. Grassley (chairman of the subcommittee) presiding.

Present: Senators Grassley, Hawkins, and Matsunaga

OPENING STATEMENT OF SENATOR GRASSLEY

Senator GRASSLEY. Good morning, everybody.

I would like to call the hearing to order. I am Chuck Grassley and I am chairman of the Subcommittee on Aging which has convened this hearing.

This morning we are going to hear testimony about osteoporosis. Now, before I start my statement, I first of all want to acknowledge at the outset that my colleague from Florida, Senator Hawkins, to my right, is very interested in this subject and will be chairing a major portion of this hearing because I must be at two other committee meetings this morning. She urged us to have this hearing. Her staff has been very helpful in organizing the hearing. I was happy to agree because osteoporosis and its consequences constitute a major public health problem, and I want to thank Senator Hawkins for her support and her interest.

Most of you know what we are talking about when we talk about osteoporosis. We are going to hear a lot about it later from our witnesses, but for the sake of defining it right at the start, I probably should take just a minute to say what it is from the layman's point of view. Basically osteoporosis is a condition in which bone mass decreases greatly, causing bones to be more susceptible to fracture than they otherwise would be. This condition afflicts probably somewhere in the neighborhood of 15 million Americans, overall most of whom, but not all, are women.

A researcher from the University of Iowa, my State, Dr. Mary Fran Sowers, has provided me with some data from Iowa which shows that at 68 years of age about half of Iowa's women have a bone mass level that places them at risk of fracture.

There are several reasons why we should be concerned about this condition and why this Subcommittee on Aging should particularly be concerned about it. First, this condition afflicts a lot of people and can be the source of considerable pain and anguish for those people. Although decrease in bone mass can start at a relatively

young age, people often do not become aware of it until old age when they experience a serious bone fracture which often can have catastrophic consequences.

Second, taking care of the consequences of this condition such as a hip fracture, can be very expensive. Estimates are that it can cost from $4 to $7 billion annually for the total population.

Third, some experts seem to think that this condition can be prevented and that it can also be treated. This is very important, if true, because it means that with relatively inexpensive precautions begun early enough in life, individuals can greatly reduce the chance that they might experience serious bone fractures with all the consequences that these fractures can bring.

This morning we are going to hear from a number of witnesses on several aspects of the osteoporosis problem. First we will hear from an individual who has osteoporosis and has suffered because of it. Then we will hear from various health institutes under the Federal Government for their expert testimony in regard to research and definition and prevention. Our third panel will consist of medical and scientific experts who will discuss the incidence of the disease, will address the questions of whether there are ways of diagnosing and screening for it, and we will take up the question of whether or not it is possible to prevent or treat it.

Our purpose this morning is to help make the general public more aware of this problem, and more importantly, what to do about it and more aware of the strengths and weaknesses of the various preventive and therapeutic methods. This subcommittee has tried to help already in this through the introduction of Senate Joint Resolution 61 which designated the week of May 20 through May 26, 1985, as National Osteoporosis Awareness Week. This was a resolution which I and Mrs. Hawkins and other members of this subcommittee introduced and supported.

Today one of our goals is to produce a very thorough hearing record which contains reliable information for individuals who want to take steps themselves to prevent this condition. Now, there may be scientific disagreements with respect to some or maybe even all of the topics we will discuss. Therefore, I hope that we can be sure that the testimony and questions to the witnesses will clearly indicate when there is a controversy on some point. Beyond our goal of increasing public awareness and producing a hearing record which helps in this way, we want to look into Federal research and public education to see if enough is being done. In addition, we want to see what is being done by private organizations and see if they have any suggestions for us as to what we can do to help with this problem.

I would like to ask unanimous consent that a statement from our colleague in the House of Representatives, Olympia Snowe, be inserted in the record at an appropriate place. Ms. Snowe has been very interested in this issue and was a primary House sponsor of the already referred to Senate Joint Resolution 61.

As I stated in the opening of my comments, Mrs. Hawkins, the Senator from Florida, has been very instrumental and has blazed a trail in this area, and I would turn to her now for her opening comments and also to publicly thank her not only for that but for her efforts in helping us conduct this hearing today in my absence.

Senator HAWKINS. Thank you, Mr. Chairman.

I appreciate your cooperation and your interest in this subject as chairman of this Aging Subcommittee. I know of no other topic that should be taking up our time and thought, or that is more important in relation to the aging and the graying of America than the subject of osteoporosis. The National Institutes of Health estimate that up to 20 million women suffer from this condition. Continuing loss of strength and resiliency in the bones leaves victims vulnerable to painful and debilitating bone fractures. Today close to 200,000 hip fractures per year are estimated to be attributable to osteoporosis.

This disease also strikes the spinal column, causing the vertebrae to collapse. The National Institutes of Health estimate that the medical costs associated with osteoporosis run at about $4 billion each year. This disease is a serious public health problem.

I am concerned with several issues that arise in connection with osteoporosis. Each of these issues is best framed by questions we will address today. What does this disease mean for those who already suffer its effects? What happens in their daily lives? What can be done to improve their condition? Are there any warning signs? How can this disease be diagnosed? How can it be treated? How much does the treatment cost? What does the latest research reveal? What can be done to prevent osteoporosis, if anything? What effect will the demographic trend toward an older population have on future health costs and, most important, what is being done to communicate the knowledge we already have about osteoporosis to the public? All of these questions are being asked by those who are afraid they may have osteoporosis or believe that they have a risk of developing it.

Concern over osteoporosis is clearly justified. It is easily ranked with arthritis and high blood pressure as one of the most prevalent chronic diseases. Arthritis is estimated to afflict 27 million men and women, and, as I have stated earlier, osteoporosis is estimated to affect up to 20 million women in the United States. Approximately 25 million men and women suffer from high blood pressure. So many Americans are susceptible to osteoporosis that accurate information about this disease needs to be easily available. Without it people are being asked to make risky decisions about their lifestyle or medical treatment. For those who disregard the seriousness of this problem, consider the following estimates. There are over 200,000 hip fractures each year in the United States; 66 percent of all hip fractures occur in women age 65 or over; 61 percent of women between age 55 and 64 are osteoporotic. That figure rises to 76 percent of women between age 64 and 74. The rate of mortality within 1 year after a broken hip approaches 20 percent. So it can be a deadly disease.

New research indicates that serious bone loss begins in women at a much earlier age than had previously been taught. What impact these findings will have on previous thinking it is too soon to tell. One important thing we know is that osteoporosis is to some degree preventable. Proper diet and exercise from childhood through middle age are very important in fighting the loss of bone strength due to osteoporosis.

Think of the irony. A nation that produces so much food that the Government is forced to purchase the surplus has a virtual epidemic among its citizens due, in part, to bad dietary practices. The time to address this problem is now. As America's population grows older, the suffering due to osteoporosis will continue to grow. Unless we act, the strain on Federal resources that ensure medical care for the aged will increase.

Research on osteoporosis has been underway for 20 years or more. The public education effort, however, is just beginning. This hearing marks a new effort to understand and highlight this issue, and I commend the chairman for having these hearings and look forward to compiling the record of today's witnesses. Thank you.

Senator GRASSLEY. Thank you very much, and I have one or two administrative announcements to make before we go to Miss Long, our first witness.

For the benefit of every witness, you can keep talking when the green light is on. We have asked witnesses to summarize and your entire statement will be printed in the record. So you will not have to worry about it. Anything you want to say will be there for the record. But as a matter of convenience to everybody who has taken time out of their busy schedules to be with us, we feel we should enforce the 5-minute rule. When the red light comes on, then we would ask you to finish your thought, not necessarily stop right at that minute, but please just sum up very quickly and then we want to go to questions.

I would also like to say that Mrs. Hawkins' staff and my staff have received a number of phone calls from people who have expressed an interest in this hearing, and for that reason we intend to keep the hearing record open for 15 days for those individuals and groups who would like to submit material for the record. Additionally, each witness should expect questions in writing from members of the subcommittee who cannot be here as well as any followup questions I or Mrs. Hawkins might have.

At this point we will receive for the record statements by Senators Pell and Metzenbaum and Congresswoman Snowe.

[The prepared statements of Senators Pell and Metzenbaum and Congresswomen Snowe follow:]

STATEMENT BY SENATOR CLAIBORNE PELL

BEFORE THE SUBCOMMITTEE ON AGING

JUNE 20, 1985

Mr. Chairman, I would like to commend you for convening this hearing today to better inform this Subcommittee about a very painful disease, osteoporosis.

Osteoporosis, as we know, has been with us for a great number of years but it is only in the recent past that we are becoming more aware of it and the pain and suffering it has caused for a large number of our older citizens, especially our older women.

It is estimated that Osteoporosis and generative bone conditions strike between 15 and 20 million persons in the United States. Approximately 25 per cent of all women over the age of 45, that is, one out of every 4 women, can be expected to suffer from osteoporois. It is further reported that approximately 50,000 women die each year from the complications that develop as a result of hip fractures and other physical disabilities caused by this dreadful disease.

I believe these statistics are horrifying, especially in light of the fact that this disease is preventable.

In my state of Rhode Island, the number of elderly citizens is increasing rapidly. My state's percentage of elderly citizens is only second to the percentage of elderly citizens in the state of Florida with the largest number of elderly residents and only slightly higher than the percentage of elderly citizens in the Chairman's state of Iowa.

These figures are important because they show that our country is growing older. A great many more of our citizens are living to an older age. I believe those years should be their best years. But the rapid increase in the number of our elderly citizens mean that a great many more will be suffering from this dreadful disease.

I believe because our population is growing older, we must focus our attention on this painful and deforming disease. We, also, must agree, and I believe today's testimony will help to move us in that direction, that the federal government should play a more prominent role in helping to prevent osteoporosis.

The major impediment to preventing osteoporosis is the lack of public information and awareness concerning the disease. It is estimated that more than three-fourths of all American women know nothing about this disease. I believe that we should take a lead

role in informing and educating our citizens about the disease, the effective treatment of it, and most importantly, the effective prevention of it through diet and exercise.

I believe, and it is my sincere hope, that hearings, such as this one, will be an important step toward preventing this disease by informing all our citizens about the ways to treat and prevent this painful and deforming disease. I, further, hope that after receiving this testimony, this subcommittee can determine the most effective way for the federal government to ensure that this disease no longer threatens our citizens.

SUBCOMMITTEE ON AGING

HEARING ON OSTEOPOROSIS
THURSDAY, JUNE 20 - 9:30 A.M. - SD 430

OPENING STATEMENT
SENATOR HOWARD M. METZENBAUM

Osteoporosis is a major public health problem which affects as many as 20 million Americans. More than one-fourth of American women have this bone-weakening disease, or will develop it. It has become a "silent epidemic" that shortens both stature--and life itself. It develops over a period of many years; beginning at about age 35, almost everyone starts losing bone, but women have less bone mass to begin with, and lose it faster than men.

The risk of osteoporosis then increases with age, and women's greater longevity contributes to the higher female to male ratio. With the graying of America, and the increasing proportion of older women, osteoporosis is a significant disabling and disfiguring health problem, especially for women.

About 1.3 million osteoporosis fractures occur annually in persons 45 and older. Many patients never recover normal activity, and the death rate approaches 20% usually within the year. The cost of osteoporosis in the U.S. has been estimated at 3.8 billion annually.

There is still much to learn about the disease. Research is needed on the causes, prevention and treatment of this epidemic, and on the risks and benefits of estrogen therapy. But enough is known, even now, to suggest that osteoporosis is a preventable condition,--if you start early enough. That means that we must commit ourselves to public education about nutrition and exercise and lifestyle.

The National Institutes of Health have taken a lead in bringing osteoporosis to public attention, and should be commended for the comprehensive consensus development conference held last April. The consensus panel issued prevention guidelines, and the lay and professional press reported them, adding to the general knowledge of the public.

National organizations such as the American Association of Retired Persons are also conducting public education campaigns.

Our young people need to be informed, too--to know that the years between 20 and 35 are probably the optimum period to stimulate new bone formation by exercise and proper nutrition, and the optimum period to develop the healthy lifestyle that can prevent osteoporosis. Adolescence is not too early to begin either.

I've been a strong advocate of food labeling--to require uniform accurate labeling of foods we consume, --because I believe that consumers need to know what's in the foods they eat, and they need to know the hazards of chemical additives like aspartame, for example. But consumers also need to know what they need to consume to prevent hazards like osteoporosis. They need information about the RDA, the Recommended Daily Allowances, of important nutrients, and they need to know how to use the grocery store rather than the drug store to fulfill those requirements.

Until research can provide more answers about causes, and treatment, our greatest hope lies in public awareness and prevention.

JUNE 20, 1985

CONGRESSWOMAN OLYMPIA J. SNOWE

STATEMENT BEFORE
THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
SUBCOMMITTEE ON AGING
OSTEOPOROSIS

MR. CHAIRMAN, I WOULD LIKE TO THANK YOU FOR GIVING ME THE OPPORTUNITY TO PROVIDE TESTIMONY FOR THIS COMMITTEE HEARING. I WOULD ALSO LIKE TO COMMEND YOU FOR HOLDING HEARINGS ON OSTEOPOROSIS, A CONDITION OF GREAT IMPORTANCE TO WOMEN.

AS THE AUTHOR OF THE HOUSE BILL WHICH DESIGNATED THE WEEK OF MAY 20 TO 26 AS "NATIONAL OSTEOPOROSIS AWARENESS WEEK," I HAVE LONG BEEN CONCERNED ABOUT OSTEOPOROSIS BECAUSE IT AFFECTS SUCH A LARGE NUMBER OF AGED WOMEN. THERE ARE 45 MILLION WOMEN IN THE UNITED STATES OVER THE AGE OF 40. THAT IS 20 PERCENT OF OUR POPULATION. SINCE OSTEOPOROSIS AFFECTS EVERY FOURTH WOMAN AFTER MENOPAUSE, WE ARE CLEARLY TALKING ABOUT MILLIONS OF WOMEN WHO ARE AT RISK OF DEVELOPING THIS DISEASE.

I FIRST BECAME INTERESTED IN THE CONDITION OF OSTEOPOROSIS WHEN I LOOKED AT THE NURSING HOME POPULATION IN RELATION TO MY ALZHEIMER LEGISLATION. APPROXIMATELY 50 PERCENT OF THE NURSING HOME POPULATION IS SAID TO SUFFER FROM ALZHEIMER'S DISEASE AND RELATED DISORDERS.

I THEN BEGAN TO WONDER WHAT LED TO THE INSTITUTIONALIZATION OF THE OTHER 50% OF THE NURSING HOME POPULATION. ALTHOUGH THE EXACT FIGURE IS UNAVAILABLE, A DISPROPORTIONATE NUMBER OF THIS POPULATION BECAME INSTITUTIONALIZED BECAUSE OF A BROKEN HIP BONE THAT NEVER QUITE HEALED. OSTEOPOROSIS IS MOST OFTEN THE REASON FOR THE BROKEN BONES. WHEN THE INDIVIDUAL LOSES MOBILITY, HE OR SHE CAN NO LONGER MANAGE ALONE IN THE COMMUNITY. MANY OLDER PEOPLE ARE CONFINED TO A WHEELCHAIR BECAUSE THEIR FRAIL BONES NEVER ALLOW THEM TO REGAIN THEIR ABILITY TO WALK.

BUT FOR EVERY ONE OSTEOPOROTIC RESIDENT IN A NURSING HOME, THERE ARE HUNDREDS MORE WOMEN IN THE COMMUNITY.

BECAUSE OSTEOPOROSIS CANNOT BE CURED, IT BECOMES ABSOLUTELY ESSENTIAL THAT WE EDUCATE WOMAN ABOUT HOW TO AVOID DEVELOPING OSTEOPOROSIS IN THE FIRST PLACE.

WE HAVE ALWAYS TAKEN OUR BONES FOR GRANTED. OUR INCREASING KNOWLEDGE OF OSTEOPOROSIS TELLS US THAT WE MUST CHANGE OUR PERCEPTION AND HELP OTHERS TO CHANGE THEIRS. THE FACT IS THAT WE MUST TAKE CARE OF OUR BONES - ALL 206 OF THEM. MILK IS NOT ONLY FOR BABIES AND GROWING CHILDREN. OUR NEED FOR CALCIUM NEVER DIMINISHES. IT IS IMPORTANT THAT AS CHILDREN AND YOUNG ADULTS WE BUILD UP OUR BONE MASS TO SUSTAIN US IN THE LATER YEARS. WE REACH OUR MAXIMUM BONE MASS AT AROUND AGE 35 AFTER WHICH WE GRADUALLY START TO LOSE CALCIUM FROM OUR BONES. SLOW, GRADUAL BONE LOSS OCCURS NATURALLY WITH AGING IN BOTH MEN AND WOMEN. HOWEVER, WOMEN LOSE BONE SOONER THAN MEN; WOMEN AT AGE 80 WILL HAVE LOST 50% OF THEIR BONE MASS COMPARED TO 14% FOR MEN.

ARE WOMEN BECOMING MORE AWARE OF OSTEOPOROSIS? A SEARCH OF THE POPULAR PERIODICALS FOR THE LAST FIVE YEARS REVEALED THAT THERE INDEED HAS BEEN A MARKED INCREASE IN THE NUMBER OF ARTICLES PUBLISHED.

IN ALL OF 1980, ONLY ONE ARTICLE WAS PUBLISHED AND THAT WAS IN A POPULAR SCIENCE MAGAZINE. NOT UNTIL 1982 DID A FEW PUBLICATIONS, SUCH AS HOUSE AND GARDEN, HEALTH, McCALL AND VOGUE PICK UP ARTICLES ON OSTEOPOROSIS - TOTALLING FIVE ARTICLES FOR THAT YEAR.

In 1983 and 1984 the number of published articles rose to 9 and 12, respectively. September 1984 was the peak month for publicizing osteoporosis with a total number of five articles in many of the major women's magazines.

A steady stream of information has been published since, and I hope it will continue. It is important that women as consumers of health care learn about osteoporosis, not only because this knowledge will lead to changed behavior, but also because it will lead women to ask questions of their doctors requiring physicians to keep up with the latest knowledge on the subject.

How can a woman best take care of preventing osteoporosis? Studies have shown that 80 percent of bone fractures resulting from thinning of the bones can be avoided with increased intake of calcium and estrogen, and 50 percent of all fractures could be avoided with the use of calcium alone. A woman therefore needs a diet high in calcium all of her life, and she needs to exercise regularly. Women should also have their bone density measured in order to know the status of their bone health.

THE DEPARTMENT OF PUBLIC HEALTH'S OFFICE OF HEALTH TECHNOLOGY ASSESSMENT IS CURRENTLY CONDUCTING A STUDY OF THE VARIOUS TYPES OF EQUIPMENT DESIGNED TO MEASURE BONE DENSITY. CT SCANS, SINGLE PHOTONS, DUAL PHOTONS AND OTHER FORMS OF DENSOTOMETRY ARE BEING STUDIED FOR THE PURPOSE OF DETERMINING EFFECTIVENESS IN DETECTING OSTEOPOROSIS. THIS STUDY WILL BE SUBMITTED TO THE HEALTH CARE FINANCING ADMINISTRATION WHO WILL USE THE INFORMATION TO DETERMINE WHICH TYPE OF DENSOTOMETRY MEDICARE WILL REIMBURSE.

MY HOPE IS THAT WHEN THE FINDINGS ARE CONCLUDED, RATHER THAN RECOMMENDING THE LARGE EXPENSIVE CT SCAN EQUIPMENT WHICH IS TOO COSTLY A TEST FOR ROUTINE USE, A LESS EXPENSIVE METHODOLOGY WILL BE RECOMMENDED AND THAT SUCH TESTS WILL BECOME A ROUTINE PART OF THE PHYSICAL EXAM FOR WOMEN, EVEN BEFORE THEY REACH MENOPAUSE.

SOME OF THE LATEST RESEARCH BY INVESTIGATORS WHO PREVIOUSLY STUDIED CALCIUM LOSS BY ASTRONAUTS LIVING UNDER WEIGHTLESS CONDITIONS INDICATES THAT WE CAN BEGIN TO PREDICT SUSCEPTIBILITY TO OSTEOPOROSIS IN WOMEN BY MEASURING THE BONE DENSITY IN THE HEAL OF THE FOOT AT SEVERAL POINTS IN TIME, AND THEN COMPARE THE RESULTS.

THIS TYPE OF LOW RADIATION SINGLE PHOTON DENSOTOMETRY SHOULD BECOME PART OF A WOMAN'S HEALTH PREVENTION PROGRAM AFTER AGE 55. THESE TESTS ARE NOT EXPENSIVE YET UNLESS THEY COME UNDER 3RD PARTY PAYMENT, THEY ARE NOT LIKELY TO BE ROUTINELY PERFORMED OR REQUESTED BY WOMEN. CURRENTLY, MEDICARE PART B AND MOST PRIVATE INSURANCE COMPANIES ONLY COVER DENSOTOMETRY FOR DIAGNOSTIC AND TREATMENT PURPOSES.

OTHER INVESTIGATORS ARE WORKING ON BLOOD TESTS AS A WAY OF PREDICTING OSTEOPOROSIS - A METHOD WHICH CERTAINLY SOUNDS PROMISING BECAUSE IT COULD BECOME PART OF A WOMAN'S REGULAR CHECKUP.

WITHOUT A DOUBT WE NEED TO FURTHER THE EDUCATION OF WOMEN ABOUT OSTEOPOROSIS AND WE NEED TO FOCUS OUR RESEARCH DOLLARS ON THE VARIOUS METHODS OF PREVENTION, TREATMENT AND PERHAPS EVEN A FUTURE CURE FOR THIS DEBILITATING BONE CONDITION.

THANK YOU MR. CHAIRMAN, THIS CONCLUDES MY STATEMENT AND I WILL BE HAPPY TO ANSWER ANY QUESTIONS.

Senator GRASSLEY. We will now hear from our first witness, Bernice Long, who will tell us about her firsthand experience with osteoporosis. She also works with the American Association for Retired Persons and will return later in the hearing to tell us about the association's involvement with the condition and efforts to educate the public.

Would you wait just a moment. A very important member of this committee, the President pro tem of the Senate, Chairman Strom Thurmond, cannot be with us because he is a member of this committee and he has to be where I have to be in about 5 minutes. We are going to vote on the nomination of Brad Reynolds to be Assistant Attorney General, and he asked if I would read a statement which is one-page long:

I would like to take this opportunity to thank you and Senator Hawkins for your efforts to increase public awareness of osteoporosis. Certainly a disease which afflicts 15 to 20 million persons in the United States should be better understood. I am sure that the distinguished witnesses who are here today can enlighten the American public to the threat posed by this major health problem.

This year, I was an original cosponsor of a Joint Resolution which established National Osteoporosis Awareness Week. On February 22, 1985, this legislation was referred to the Senate Judiciary Committee, which I chair. The Judiciary Committee promptly reported this resolution with a favorable recommendation to the full Senate. After passage by the Senate and House, this legislation was enacted into law by President Reagan on May 20, 1985.

I am proud to have had a role in the passage of this law. Hopefully, the designation of May 20, 1985 through May 26, 1985, as National Osteoporosis Awareness Week, and the public hearing which is being conducted today, will lead to a greater commitment in this country to the treatment and prevention of osteoporosis.

Because of prior scheduling conflicts, I regret that I was not able to attend the hearing today. However, I thank all of the fine witnesses who have given unselfishly of their time to be here, and I look forward to reviewing the testimony the Subcommittee will receive today.

Now, after reading Senator Thurmond's statement into the record at his request, I now turn to Miss Long.

STATEMENT OF BERNICE LONG, HEALTH ADVOCACY STATE COORDINATOR FOR TENNESSEE AND VICTIM OF OSTEOPOROSIS

Miss LONG. Good morning, Members of the U.S. Congress and concerned Americans who are here today.

Osteoporosis is a very sneaky illness. It is not a disease. It is a condition. But like diabetes it comes on quietly, unobserved, without warning over a long period of time until one day something happens and suddenly you find out that you have osteoporosis.

But you also learn that there is nothing that you can do to prevent it and there is nothing that you can do for an absolute cure, but you learn that you will have to live with it and you will have to change your lifestyle. I know because this condition caught me by complete surprise; 3 years ago I lifted a heavy box from the trunk of my car and I heard my spine snap like a twig and I went down, and that is when I learned that I had osteoporosis. But I had absolutely no prior warning that I had osteoporosis, a gradual thinning of the bones that makes them very susceptible to fractures.

The thing that disturbed me was that even though I had had annual medical checkups for many, many years, no one had even mentioned that I was developing a calcium deficiency or that I was a potential candidate for osteoporosis. I think the failure of diagno-

sis is probably due to the fact that regular x rays do not show anything until there has been a 30 percent loss in bone density; and since I had no symptoms, other more sensitive methods for evaluating bone condition were not prescribed.

I cannot describe to you the pain I experienced with that fractured spine. You can only begin to imagine what it was like. During the days that followed when I was bedridden, I had time to reflect upon the surprising turn of events in my life and to wonder about the condition of osteoporosis—a word that I had never heard before and probably did not even know how to spell.

So I began to ask questions about it and that is when I first discovered that osteoporosis poses a very serious threat to one-quarter of the women over 40 years of age, which amounts to 15 to 20 million older Americans. And although I was very aware of the price that I was paying for my treatment, I was shocked to learn that in the United States this condition costs an estimated $6 billion in health care expenditures annually. I must point out that this is a direct drain upon the Medicare funding as a result.

Why had I not heard of such a major public health problem? I was frightened to learn that the condition can be fatal when hip fractures leave a person bedridden. The resulting isolation, depression, and malnutrition can end in death. Mortality during the year following a hip fracture may be as high as 15 to 30 percent in the United States. It is usually caused by such complications as pneumonia, and of the people who survive, many fail to return to independent living.

With this frightful knowledge, I was determined to find out if my condition could be treated. I was determined to get back on my feet and to find a way to lead as normal a life as possible. In addition, I was determined to warn other women what could happen to them. In other words, I was determined to be a survivor.

At the time that I fractured my spine I was working, and 72 years of age; I became 75 yesterday. This is my birthday present, coming to you today. At 72 I was working and I was the administrator of a very large law firm. So it was important to me that I get back to my job. In order to manage my daily activities, so as to avoid accidents that could cause additional fractures, I was fitted with a brace, a body brace which I wore for 3 months. In addition, I purchased a cushion especially made for back problems, a very long cushion which has contours to fit my back. Believe me, I lived with that cushion, because that cushion traveled with me to my office, to my car, to my home, and back. We were inseparable for a year at least.

I will tell you about the treatment and management of osteoporosis when I make another presentation later in the morning, but now I am going to tell you that I have my osteoporosis under control and I have become actively involved in an effort to inform other women of this condition and to convince them that they must make changes in their daily habits in order to prevent osteoporosis. If I had only known these preventive measures myself; if I had only known to take in 1,500 milligrams of calcium each day and to adopt a diet of calcium-rich foods.

Until recently osteoporosis was rarely heard of among the general public and it was greatly misunderstood. It was generally

thought our grandmothers naturally developed brittle bones as they grew older and we heard for years about the dowager's hump. No one knew exactly why it was called that, but we had all heard about it. In fact, osteoporosis is a condition which is most common to white or Asian women over 45. I understand that women who are very fair-skinned, tall, slender, small-boned are the most susceptible and I knew that I was in that category.

Because of my experience and that of other women who are similarly ignorant of their calcium deficiency, I am working with the American Association of Retired Persons as the State Health Advocacy Services Coordinator for Tennessee to help Americans learn about osteoporosis, what it is, who is the most likely to have the disease, how it can be diagnosed early, what is the most effective treatment and, most importantly, how can it be prevented.

The American Association of Retired Persons believes that our society has an obligation to provide high-quality health care at a fair price and, therefore, in 1984 the AARP launched a national campaign to save and strengthen our Nation's health care system. The campaign is called Healthy US, and it seeks to "Cut the Costs and Keep the Care" in our health care system. One of the goals of the AARP health care campaign for 1985 is to help Americans obtain vital information about their own health and practice more healthful lifestyles.

The promotion of better understanding of osteoporosis by women of all ages has been identified as one way that the AARP members can achieve this goal. Osteoporosis awareness was selected as a health care campaign action step for the month of May and, accordingly, the AARP actively supported Congresswoman Snowe's resolution to declare a week in May as National Osteoporosis Week. The AARP has published an educational poster, and I have it here today, which I would like to show to you, an excellent publication. Excellent. Also we have published what we call the Calcium Cookbook, equally excellent. These are to help women to better understand osteoporosis, its risk factors, diagnosis, treatment, and prevention.

We are encouraging the AARP chapters and the retired teacher units all over this country to sponsor educational activities using these materials to help older persons to learn how to recognize the symptoms of osteoporosis and ascertain their risk of developing this condition. We are also encouraging other activities such as declaration of a local or State osteoporosis awareness day or a week, osteoporosis exhibits at health fairs, cooking contests featuring foods high in calcium and vitamin D, and bone and muscle-building exercise classes.

And I do want to say here on the point of exercise that it must be a limited type. However, walking—I ride a stationary bicycle. Excellent. But you must be very careful about exercise.

We are also encouraging public forums to alert people of all ages about this condition. We are encouraging our members to ask their physicians more about osteoporosis in an effort to encourage health care professionals to respond to consumers' needs for information and guidance. I do want to say that part of this campaign is to encourage physicians all over this country to be more conscientious about alerting the women that come to them for assistance, to alert

them that they may have a calcium deficiency because it can develop on down the line 25 years, and at that time it is too late to do anything about it.

We believe that it is of the utmost importance to help younger women to understand how to prevent it, and, therefore, we are distributing nationally the poster and the cookbook to women's organizations, health organizations, health providers, health fairs and conferences and universities in an effort to reach all women.

I will speak to you again later this morning as part of a panel, and at that time I will give you further details on the prevention and the management of osteoporosis. Thank you very much for your attention.

[The prepared statement of Miss Long and responses to questions submitted by Senators Grassley and Metzenbaum follows:]

AARP

Statement

of the

American Association of Retired Persons

on

Osteoporosis

June 19, 1985

Bernice Long
Health Advocacy State Coordinator
for Tennessee

Osteoporosis Public Hearing -- Testimony

Part 1: Opening Remarks (5 minutes)

Good morning -- members of Congress and concerned Americans. Osteoporosis is a very sneaky disease. I know because it caught me by surprise. Three years ago, I fractured my spine. I had no prior warning that I had the disease osteoporosis, a gradual thinning of the bones, which makes them susceptible to fractures. Even though I had yearly medical check-ups, no doctor had mentioned my worsening physical condition. I now know that the failure to diagnose my disease earlier was partly due to the fact that regular X-rays do not show anything until there has been a 30% loss in bone density. Since I had no symptoms, other more sensitive methods for evaluating bone condition were not prescribed.

I can not describe to you the pain I experienced with a fractured spine. You can only begin to imagine what it was like. During the days I was bedridden, I had plenty of time to reflect upon the surprising turn of events in my life and wonder about this disease -- osteoporosis, a word I had never heard before, and could barely pronounce. I began to ask questions about the disease and discovered that it poses a serious threat to one-fourth of women over 40 years of age, amounting to 15-20 million older Americans. I was very aware of the price I was paying for my treatment but was shocked to

learn that, in the U.S., the disease costs an estimated $6 billion in health care expenditures, annually. Why had I not heard of such a major public health problem, I wondered. I was frightened to learn that the disease can be fatal when debilitating hip fractures leave a person bedridden. The resulting isolation, depression and malnutrition can end in death. Mortality during the year following a hip fracture may be as high as 15-30% in the U.S., usually caused by such complications as pneumonia and pulmonary emboli. Of the people who survive, many fail to return to independent living.

With this frightful knowledge, I was determined to find out if my condition could be treated. I was determined to get back on my feet and find a way to lead as normal a life as possible. And in addition, I was determined to warn other women of what could happen to them.

I have received treatment for my condition and I have learned ways to manage my daily activities in such a way as to avoid accidents which might cause additional fractures. I will describe the treatment and management of osteoporosis in more detail when I make another presentation later this morning. Now that I am back on my feet I have become actively involved in an effort to inform other women of the disease and to convince them to make the changes in their daily habits which will help prevent osteoporosis. If only I had known to take these preventive measures!

Until recently, osteoporosis was rarely heard of among the general public and greatly misunderstood. It was generally thought that our grandmothers naturally developed brittle bones as they grew older. In fact, osteoporosis is a disease, most common to white or Asian women over 45 -- a disease which can be diagnosed much earlier than it was in my case -- a disease which can be prevented and treated. Because of my experience and that of many other women who are similarly ignorant of their worsening physical condition, I am working with the American Association of Retired Persons, as the State Health Advocacy Coordinator for Tennessee, to help Americans learn about osteoporosis -- what it is; who is most likely to have the disease; how it can be diagnosed earlier; what is the most effective treatment; and, most importantly, how it can be prevented.

The American Association of Retired Persons believes society has an obligation to provide high quality health care at a fair price. Therefore, in 1984, AARP launched a national campaign to save and strengthen our nation's health care system. The campaign is called "Healthy US" and seeks to cut the cost and keep the care in our health care system. One of the goals of AARP's Health Care Campaign for 1985 is to help Americans obtain vital information about their own health and practice more healthful lifestyles. The promotion of a better understanding of osteoporosis has been identified as one way AARP members can achieve this goal. Osteoporosis awareness was selected as the Health Care Campaign Action Step for the month of May. Accordingly, AARP actively supported Congresswoman Snowe's resolution to declare a week in May as "National Osteoporosis Week." AARP has published an educational poster with its accompanying "Calcium Cookbook" to help women better understand the disease

osteoporosis -- its risk factors, diagnosis, treatment and prevention. We are encouraging AARP chapters and units to sponsor educational activities, using these materials, to help older persons learn how to recognize the symptoms of osteoporosis and ascertain their risk of developing the condition. We are also encouraging other activities such as: declarations of a local or state "Osteoporosis Awareness Day (or Week)"; osteoporosis exhibits at health fairs; cooking contests, featuring foods high in calcium and vitamin D, and bone and muscle-building exercise classes. We are encouraging members to ask their physicians more about osteoporosis in an effort to encourage health care professionals to respond to consumer needs for information and guidance. We also believe that it is of utmost importance to help younger women understand how to prevent osteoporosis. Therefore, we are distributing the poster and cookbook to women's organizations. health organizations, health providers, health fairs and conferences in an effort to reach all women.

I will be speaking to you again this morning as part of a panel. At that time I will give you further details on the prevention and management of osteoporosis.

Thank you for your attention.
Are there any questions?

Osteoporosis Public Hearing -- Testimony

Part 2: (5 minutes)

The American Association of Retired Persons has two important messages to send through its osteoporosis awareness program. The first message is for older women who may have osteoporosis and not even know it. This message emphasizes early detection of osteoporosis and lifestyle management for the osteoporotic patient. The second message is for younger women as well and emphasizes how relatively simple changes in one's lifestyle can help prevent osteoporosis.

First, our message regarding early detection of osteoporosis. We begin by alerting our membership as to which people are most likely to develop osteoporosis. Women of northern European or Asian descent, who are thin, smoke cigarettes, or have relatives with the disease, are the most likely candidates. We encourage these women particularly to ask their doctor about tests for diagnosing osteoporosis early.

Unfortunately, osteoporosis is hard to detect because the disorder has so few symptoms. X-rays do not reveal bone loss until there is 30% decrease in bone density. In recent years, more sensitive diagnostic procedures have been developed, such as absorptiometry, bone biopsy, and laboratory testing. These methods are relatively expensive, however, and limited to major medical centers. I believe that it is very important that these screening methods become more readily available. I would

recommend that regular bone scanning be started at about age 45, as a method for early diagnosis.

We also suggest that women keep careful records of any changes in their height. Losing several inches in height, especially when this loss of height is accompanied by changes in posture and back pain, is an outward sign of the spinal fractures characteristic of osteoporosis.

Once osteoporosis is diagnosed, it is important to minimize the chances of breaking bones. Therefore, in addition to stressing the importance of early diagnosis, our message to older women also suggests a lifestyle management plan to eliminate unnecessary hazards which might lead to accidents and broken bones. We suggest that people take the following precautions: 1) remove all loose wires, cords, and throw rugs; 2) install safety rails in bathrooms and along stairs; 3) minimize clutter; 4) make sure all stairways are well lit; 5) wear sturdy, rubber-soled shoes; 6) avoid icy or highly polished surfaces; 7) turn on the lights if you get up in the middle of the night; and 8) monitor, with your doctor, the use of drugs that cause sleepiness or dizziness.

As another precaution, we suggest that older women, and particularly osteoporotic patients learn to sit and move in a way which avoids putting too much stress on the spine. Older women tend to have sedentary habits and often relax in an easychair or bed propped up with pillows. This aggravates osteoporosis.

Instruction in body mechanics, posture and back-strengthening exercises will help these women to stand straight, sit straight and lie straight, thus relieving pressure on the spine.

There is considerable controversy regarding the various treatment methods now available for osteoporotic patients. We encourage women to evaluate the risks and benefits of each therapy thoroughly with her physician. Estrogen replacement therapy is one treatment method which is controversial but is known to prevent approximately 90% of vertabral deformations. In addition to effecting bone metabolic processes, estrogen enhances calcium absorption and lessens the excretion of calcium. When amounts of this hormone are decreased at menopause, not only is less calcium absorbed but more of it is excreted, accelerating bone loss. Some physicians are reluctant to prescribe estrogen because it has been associated with adverse side effects, such as endometrial cancer. Skin patches and other advanced methods of administering estrogen, possibly combining dosss with progesterone, may eliminate many of these risks, however.

Sodium flouride treatment is another controversial method which increases bone mass. But its use is still experimental and may cause harmful side effects. The new bone may not be stronger but may be more brittle and thus weaker.

Now to the second message of AARP's osteoporosis awareness program. It is important to alert everyone to the fact that all people begin to lose some bone as early as age 35. In fact, younger women who have had their ovaries removed, and therefore have less estrogen in their system, may develop osteoporosis long before they reach old age. Therefore, everyone should be concerned about bone-strengthening exercise and calcium intake, sufficient to build the maximum bone mass during the bone-formation years and assure greater bone mass during the later years.

Once again, the key to preventing osteoporosis is to maximize peak bone mass and to minimize the rate of bone loss in later years. By making the necessary changes in one's diet and exercise patterns, everyone can start a lifelong prevention program. But it's more complicated than merely drinking more milk and doing a few jumping jacks. The following suggestions for making changes in one's diet and exercise patterns apply to older people as well as younger, with variations as described.

To maintain the ideal level of calcium in the body and maximize peak bone mass, it has been generally agreed that the pre-menopausal woman should take about 1000 mg. of calcium per day and the menopausal and post-menopausal women should take 1500 mg. per day. Although it may be difficult to get these amounts of

calcium through diet alone, women should be taught which foods have the highest levels of calcium. Dairy products are a good source of calcium, since they often have both vitamin D and lactose which aid the absorption of calcium. But many women think milk is "just for kids" or, worried about weight, they have stopped drinking milk. These women should be encouraged to drink skim milk and eat low-fat yogurt. They should also be encouraged to eat dark green leafy vegetables, sardines and salmon with edible bones, and other calcium-rich foods. Increasing intake of calcium through one's diet alone may not be enough, however, since the average American diet contains only 400-500 mg. of calcium per day. Therefore some women, and particularly older women, may need to take calcium supplements. There is controversy over what is the best source of calcium supplements, however, and women should be informed of the various options, and their pros and cons. They should learn to verify whether a calcium compound provides adequate elemental calcium. They should know that persons with chronic renal disease should limit their calcium intake. They should know that even though some women are getting their calcium supplement from antacids composed of calcium carbonate, antacids may have a short-term effect of reducing stomach acidity, but a long-term effect of increasing

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it. Further research needs to be done to determine whether these antacids make good calcium supplements. Women should be aware that aluminum-containing antacids, can cause losses of calcium from the body and are not a source of calcium.

Women should know that vitamin D helps the body absorb calcium. Younger women who spend time in the sunshine, usually get the RDA of 400 IUs of vitamin D per day with no problem. But they should know that more than 600-800 IUs of vitamin D per day can be harmful. Older women, especially those who, because they are housebound or confined to an institution, have a low exposure to sunlight, may have a vitamin D deficiency. In addition, inadequate conversion of vitamin D to calcitriol, an active metabolite of vitamin D necessary for calcium absorption, is thought to be responsible for the decline in calcium absorption with aging.

As you can see, the prevention of osteoporosis through changes in one's diet is not as simple as it appears. The need for good educational materials and a public health education program on osteoporosis is evident as we review the complexities of the issue. In addition, we must teach women about the possibility that smoking and alcohol consumption may increase the possibility of osteoporosis.

Modification of one's diet is not the only preventive measure;

it is but one aspect of a total approach to maximizing bone mass and minimizing bone loss. Regular, moderate weight-bearing exercise has been shown to stimulate the formation of new bone and may also decrease the likelihood of a fall or other injury by strengthening supporting muscles and improving balance and agility. Women need to be instructed that bones require stress against gravity. Therefore, activities that place moderate stress on the spine and long bones of the body, such as walking, jogging, dancing, and cycling, are good. Although swimming is an excellent cardio-vascular exercise, it does not promote bone growth because it is not a weight-bearing activity. I have outlined for you the most important facts about osteoporosis which I believe women urgently need to know so that they can make the necessary changes in their daily habits before it is too late. Though you may not have heard of osteoporosis before, it <u>is</u> one of the most serious health issues facing older Americans today. Until people know more about the disorder and the steps they can take to prevent it, osteoporosis will continue to cause physical and emotional pain to millions of women and men. Osteoporosis will cause debilitating fractures and will result in the deaths of thousands of people each year from fracture complications.

Life expectancy for women has increased. After menopause, a major part of a woman's adult life still lies ahead. If we are to help these women lead an active life, we must encourage additional research on the metabolism of bone, the definition of risk factors, and the development of safe, effective, low-cost strategies for prevention and treatment. There are few hard and fast rules for dealing with osteoporosis and too many questions to be answered.

You're probably asking yourself a few questions -- "Do I have osteoporosis?" "Could I get it?" "What can I do if I already have it?" We, who have spoken today, have given you some of the answers. It is now up to you to find out more, to discuss osteoporosis with your doctor, and to "spread the word" to other people who might be at risk. You of the Congress of the United States are in a position to launch a major public health education campaign on osteoporosis. I, personally, speak for the American Association of Retired Persons in support of such an endeavor.

Thank you.

QUESTIONS FOR BERNICE LONG FROM SENATOR GRASSLEY

1. Question: Bernice, may I ask how old you were when you fractured your spine?

   Answer: I was 72 years old. I had never had any indication of a spinal problem and none at the time of my fracture. My height, according to the physicians' measurements, has always been 5'7". However, I had developed a "dowager's hump" which was attributed by physicians to my many years of leaning over a desk and typewriter; at no time was I told that it was characteristic of women who had osteoporosis.

2. Question: Tell us a little bit about your treatment for the spine fracture. How long were you hospitalized and how much did it cost?

   Answer: I was taken to the hospital emergency room when I fractured my spine and my family doctor was called, who in turn called an orthopedic specialist. The x-rays disclosed a diagonal fracture or "crack" across the lower spinal column. The specialist advised that it would be a matter of time to permit the fracture to heal and that I could either be admitted to the hospital to convalesce or stay in my home. I chose my home. However, I was fitted with a body brace to keep my spinal cord immobilized and which would later permit me to walk and sit. I was bedridden in my home for about ten days until I was able to move about with the aid of the body brace.

   Eventually, I returned to my office on a part-time basis at first. I had been the administrator of a large law firm, but I retired a year after the fracture incident. As I stated at the Senate hearing, I used a long, seat cushion contoured to my back, in my office chair, my car seat, and in my home for a year to avoid discomfort, and an aching back.

   My expenses, by staying in my home, were approximately $600, including my body brace and cushion. It would have been significantly more had I decided to take the option of convalescing in the hospital. The specialist prescribed large doses of calcium tablets and told me that I had osteoporosis. I had never heard of it before!

   I am confident that the urgency of returning to work was the incentive that helped me to survive the healing of the fracture.

3. Question: Did you fit the profile of those who do not maintain an adequate diet in the years leading up to your fracture?

   Answer: Yes, I think so. The inadequacy of my diet was due to the fact that I avoided for years those food items that could be considered fattening, and this included dairy products having high calcium content. I now recognize that for years I have been favoring a diet that included foods very low in calcium.

4. Question: Since prevention of osteoporosis requires beginning relatively early in life, how has AARP tried to reach the younger ages who must begin to think about this problem? The AARP membership, after all, is now fifty and over, is it not?

   Answer: The American Association of Retired Persons has published a poster/brochure and an accompanying calcium cookbook which were designed to educate younger as well as older women about osteoporosis. The poster features a strong prevention message, which was especially intended for younger women. The materials have been distributed to women's organizations and health organizations with members of all ages, as well as throughout the aging network. The materials have also been exhibited at conferences and health fairs involving young women. Bulk orders will be shipped to organizations with a particular interest in osteoporosis for distribution to their members.

5. Question: I take it that AARP has concluded that securing the active collaboration of a physician in both preventing and treating osteoporosis is a wise policy?

   Answer: Yes. AARP encourages women and their physicians to work together as a team to develop a suitable, personal program for diagnosis, prevention and treatment of osteoporosis. There are few hard and fast rules about risk factors, symptoms, diagnosis, treatment and prevention. But health professionals can provide information about various options which can guide each person to make responsible choices regarding the prevention and treatment of osteoporosis. For example, a physician can advise whether calcium supplements are necessary, can recommend facilities with the proper equipment for screening bone density, and can suggest whether or not estrogen replacement therapy or other more experimental treatments are advisable.

6. Question: Has AARP found, in studying the osteoporosis problem, that there could be a danger of oversimplifying both the problem and the prevention and therapeutic methods available to help with it?

   Answer: Yes and no. Relatively simple changes in one's lifestyle can help prevent osteoporosis. By increasing daily weight bearing exercise and the consumption of calcium rich foods at an early age, a person can contribute greatly to the prevention of osteoporosis. AARP believes that these simple changes are of utmost importance and that there is no harm in emphasizing their simplicity in order to encourage people to make such lifestyle adjustments.

   On the other hand, there is a danger of oversimplification with regard to dietary supplements and various therapeutic treatments for osteoporosis. The following precautions are examples of the complexities involved:

   1. Calcium supplements:

      - Calcium supplements made of bone meal or dolomite contain trace minerals that can have harmful side effects.

      - Some calcium-rich antacids may increase stomach acidity over the long term.

      - People with a history of kidney stones should limit calcium intake.

   2. Vitamin D:

      Too much vitamin D can be toxic. Most people get enough vitamin D, but persons who are not regularly exposed to sunlight and who have little vitamin D in their diet may have a deficiency.

   3. Estrogen Replacement Therapy:

      Although an effective treatment method, there are serious risks involved when taking estrogen. Estrogen has been linked to the incidence of endometrial cancer and to the increased risk of blood clots. Although more effective methods for administering estrogen are being developed, a physician should explain the pros and cons so that the patient can decide whether to elect this treatment option.

   4. Calcitonin and sodium fluoride:

      These treatments help increase bone mass, but their use is experimental and there are problems and negative side effects associated with each.

Osteoporosis can be treated, and the rate of bone loss slowed. Yet, it is important for women to understand that each treatment available today is the subject of debate within the scientific community, and each has pros and cons that must be considered.

QUESTIONS FOR BERNICE LONG: FROM SENATOR METZENBAUM

1. Question: Was there anything that could have been done differently to help you more?

   Answer: I am confident that I would not have osteoporosis today, if I had known at least twenty years ago of the existence of osteoporosis and the dangers of calcium deficiency. Help at 72 years old when I fractured my spine, was too late and too little. I am bitterly disappointed that, of all the physicians who had cared for me and given me periodic physical examinations for a least the past 25 years, not one of them warned me about osteoporosis or recommended preventive measures. It is my belief that the concern and cooperation of all health professionals is needed to make a concentrated effort to warn patients (particularly women) to increase their calcium intake, and exercise regularly in order to achieve a future society that has eliminated or controlled the problems of osteoporosis.

2. Question: Do you believe earlier diagnosis would have been useful?

   Answer: Early diagnosis is the key to eliminating, or at least controlling, this growing epidemic of disabling fractures. Osteoporosis is hard to detect because the disorder has so few symptoms. The problem of diagnosis is complicated by the lack of an inexpensive, convenient, and accurate means of measuring small change in bone mass. Still, the earlier osteoporosis is diagnosed and treated, the better the chances of preventing broken bones and serious disability.

3. Question: What do you believe can be most useful to you now?

   Answer: The most "useful" and the most necessary method of combating osteoporosis today, for those individuals who may or may not know they have it, is education. People must be made osteoporosis-conscious through the impact of television, news media, publications, health agencies, state commissions on aging, health forums, and the cooperation of every type of organization. Osteoporosis should become a matter of family concern for grandparents, parents and children. They must be convinced that milk is no longer a "sissy" drink and encouraged to include weight-bearing exercise such as walking, in their daily regimen. Also, our elderly must be made aware of common sense safety measures, or "the do's and don'ts" to avoid fractures! I had no business attempting to lift a heavy box from the trunk of my car but, unfortunately,

I thought I could do it. Now I even caution the bag boys at the supermarkets not to sack my groceries any heavier than I can easily lift and carry!

Surviving osteoporosis fractures depends on the individual and the general condition of one's health. I was fortunate that my case wasn't any more serious than it was; I firmly believe that this in part is due to having excellent health at 72 years of age due to my annual health checkups, vitamins and moderate exercise. It's too bad that no one cautioned me to also take additional calcium, and I did not even drink milk!

My fracture healed without any long term disability and my system responded to massive doses of calcium supplements and a high calcium diet. I am now thoroughly educated on how to survive and live with osteoporosis, but I have a deep concern for all Americans who do not know how to prevent this bone disorder, nor how to live with it! This is also the concern of the American Association of Retired Persons, not only for its twenty million members, but for all persons of this country, of all ages, and for our future generations.

AH/mjr

Senator HAWKINS [presiding]. Thank you very much. We appreciate so much your coming to Washington from Tennessee. I wish you many more happy birthdays. You can come to see us every birthday if you like. You stand as an example for so many women.

Our next panel consists of Dr. T. Franklin Williams, Director of the National Institute on Aging, and Dr. Mortimer B. Lipsett, Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. These are the two national institutes of health which work on osteoporosis.

Welcome, Doctors. We will hear from Dr. Williams first.

STATEMENT OF T. FRANKLIN WILLIAMS, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING; AND MORTIMER B. LIPSETT, M.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Dr. WILLIAMS. Madam Chairman and members of the subcommittee, I am Dr. T. Franklin Williams, the Director of the National Institute on Aging. I appreciate this opportunity to present information about osteoporosis and on the activities of the National Institute of Aging and other departmental activities related to this disease.

I have submitted written testimony and will simply summarize briefly here.

Osteoporosis, as Miss Long and Senator Grassley have already said is a disorder in which bone mass and strength gradually decrease. The disease typically progresses silently and slowly over many years. It generally does not become clinically significant until later life when it frequently becomes so severe that bones are highly susceptible to fracture. A fall or blow that would not injure a normal person may cause a fracture in a person with osteoporosis.

It is an extremely common problem among older people, especially among women. The first figure of your graphs illustrates the increasingly large proportions of older women who are found to have this condition, reaching 75 to 80 percent of those over the age of 75. Overall 20 to 30 million Americans, including both men and women, have this problem. One should keep this in mind, especially in the later years.

Various bones are predisposed to fractures and can produce pain and the disfiguring dowager's hump, as Miss Long referred to it, but hip fractures are the most serious problem. Hip fracture is primarily the problem of old people. 85 percent or more of the 200,000 hip fractures per year occur in persons over the age of 65. The second figure here illustrates the exponential increase in the numbers of people with hip fractures in the late years. A corollary of this fact is that if we could postpone the occurrence of hip fractures by 6 to 8 years, we could halve the number of incidents of this condition. The estimated cost for hip fractures is well over $7 billion per year in this country now.

Even though the condition is very widespread, it should not be accepted that this is an unavoidable consequence of old age. There are therapeutic and preventive approaches that are already recognized as useful, and our ongoing research should lead to further

improvements. Both the National Institute on Arthritis, Diabetes, and Digestive and Kidney Diseases, about which Dr. Lipsett will speak, and the National Institute on Aging are making significant efforts to encourage research on this problem. For example, the NIA is supporting studies to determine how changes in the level of estrogens and other homeowners as occur in menopausal women are related to bone loss. Other studies are addressing changes in the regulation of vitamin D with aging. The skin's capacity to make vitamin D is diminished with aging and the body's ability to activate vitamin D is also diminished. This suggests that at least some elderly people may need larger amounts of vitamin D in their diet than the current recommended dietary allowances.

Studies in calcium absorption from the intestinal tract also suggest a decline in absorption with aging, and this together with the generally decreased intake of calcium in older people means that very many old people are getting less than the optional amount of calcium needed.

The National Institutes of Health Consensus Development Panel, for example, recommended that older women should receive up to 1,500 milligrams of calcium per day. Exercise is another important factor in maintaining bone mass. Early studies are indicating that an exercise program may be effective in countering the bone loss in older women. More studies are needed to assess the long-term benefits which can be expected from exercise.

It is also becoming increasingly recognized that osteoporosis alone is rarely enough to cause hip fractures which generally occur only after trauma, typically a fall. Studies have identified a subgroup of older persons who fall very frequently. A recent conference organized by NIA identified needs for research on several visual, neurologic, and cardiovascular problems which may be important in potentially preventable causes of falls in the elderly. The NIA is active in disseminating information on osteoporosis to the general public. For example, over 1 million copies of one of our age pages, a factsheet called "Osteoporosis: The Bone Thinner," have been distributed. Another example is the current issue of the NIH News & Feature Service, copies of which have been made available to the committee, which has three articles on osteoporosis in it.

The NIA works with the American Association for Retired Persons in the distribution of information in this field and also has been very much helped by the Pfizer Corp. in the widespread distribution of information on this problem.

Other activities of the Department of Health and Human Services, which are summarized in my written remarks, include epidemiologic studies by the Centers for Disease Control on causative factors of injuries in older people and a strong interagency initiative in health promotion for the elderly led by Secretary Heckler and the Surgeon General's office.

The state of our knowledge about many of the current and proposed means of preventing and treating osteoporosis is both promising and frustrating On the one hand, we have evidence that they may be helpful in certain persons. On the other hand, we frequently do not know enough to make wellfounded recommendations about the usefulness in specific groups, especially among the elder-

ly. Research in this field has reached the point where it is possible to do the basic science studies and clinical trials that would allow us to move from tentative generalizations to more specific recommendations. Both of our institutes are collaborating with leaders in this field to plan a systematic strategy for osteoporosis research to be conducted over the next several years. We believe this research will help provide the information which the physicians and the public needs to choose the best ways of preventing or treating osteoporosis for each individual.

I will be very glad to answer any questions.

[The prepared statement of Dr. Williams and responses to questions submitted by Senators Grassley and Metzenbaum follow:]

STATEMENT BY

T. FRANKLIN WILLIAMS, M.D.
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NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTES OF HEALTH
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGING
OF THE
COMMITTEE ON LABOR AND HUMAN RESOURCES
SENATE

JUNE 20, 1985

Mr. Chairman and members of the subcommittee, I am Dr. T. Franklin Williams, Director of the National Institute on Aging (NIA). I thank you for the opportunity to present information about osteoporosis and on NIA and other Departmental activities related to this disease.

Public Health Impact of Osteoporosis:

Osteoporosis is a disorder in which bone mass and strength gradually decrease. The disease typically progresses silently slowly over many years. It generally does not become clinically significant until later life, when it frequently becomes so severe that bones are highly susceptible to fracture. A fall or blow that would not injure a normal person will cause a fracture in a person with osteoporosis.

Osteoporosis is extremely common among older persons, especially among women. Because of the gradual progression of the disorder, estimates of the number of persons affected depend in part on judgements about what extent of bone loss is significant. It is generally accepted that at least 15 to 20 million women in the U.S. have osteoporosis. The percentage of women affected rises steadily from approximately 30 percent among women aged 45 to 54, to approximately 90 percent among women over 75. It should not be forgotten that osteoporosis affects large numbers of older men as well, though it tends to become clinically significant later in

life for males, especially at ages 80 and over, as evidenced by the high rates of hip fractures among men over 80.

Osteoporosis predisposes to fractures of various bones, including vertebral crush fractures which cause pain and the disfiguring "dowager's hump." However, hip fractures are the most serious in terms of disability and mortality. Approximately one in five hip fracture victims die of complications attributable to the fracture. One year after suffering a hip fracture, 20 percent of victims cannot walk, and another 20 percent require a walker or crutches.

Hip fracture is primarily a problem of the elderly: Eighty-four percent of the more than 200,000 hip fractures per year in the U.S. occur in persons over 65. Hip fractures rates are exceedingly high among persons over 85 years old. Because of the rapid increase in this age group in the near future, the number of hip fractures among older persons will increase sharply to over 300,000 annually by the year 2000, unless there are significant improvements in prevention. Hip fractures pose a significant economic as well as a medical burden. The annual costs associated with hip fractures in the U.S. were estimated at over $7 billion in 1977, and are certainly higher today.

Research on Osteoporosis:

Though osteoporosis is extremely widespread among the elderly, it should not be accepted as an unavoidable consequence of old age. Currently, certain therapeutic and preventive approaches are recognized as useful, and ongoing research on the causes, prevention and treatment should lead to improvements in the future. NIA and the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases (NIADDK) have made significant efforts to encourage research on osteoporosis, and currently support active research programs on this problem. Some of the most promising research directions are outlined below:

In women, changes in estrogen levels following menopause appear to accelerate the rate of bone loss. NIA is currently supporting research at the Mayo Clinic, the University of Massachusetts, and other sites to determine exactly how changes in levels of estrogens and other hormones are related to bone loss. Estrogen therapy has been shown to be effective in blocking this accelerated bone loss, but many questions remain about who should receive treatment, and what dosages, combinations with other agents, and routes of administration are most safe and effective. For example, new methods of estrogen administration, such as skin patches, may avoid some problems associated with estrogen use, but need to be tested carefully.

Other changes with age besides menopause contribute to osteoporosis. This is illustrated best by the fact that osteoporosis develops in elderly men. In addition, it is believed that other factors in addition to the menopause contribute to the severe bone loss in the hip in women over 75 which is responsible for the high numbers of hip fractures in this group. Aging changes relating to two nutrients-- calcium and vitamin D-- may be especially important. The ability of the digestive tract to absorb calcium declines with age. This decline is especially significant since typical dietary intake of calcium in U.S. adults, especially the elderly, is well below the Recommended Dietary Allowance of 800 milligrams per day, and far below the 1000-1500 milligrams per day judged by a National Institutes of Health Consensus Development Panel to be needed for adequate calcium balance in women.

There also appear to be changes with age in the regulation of vitamin D, which is converted by the body to an active form required for adequate bone mineralization. Part of the body's vitamin D supplies are made in the skin in response to sun exposure. Research supported by NIA has shown that the capacity of the skin to make vitamin D is diminished in the elderly. In addition, the body's ability to activate vitamin D appears to be diminished in the elderly.

Recent results from a study supported by NIA at the University of Washington reinforce the idea that deficiencies in calcium and

vitamin D are important in osteoporosis. In a significant proportion of osteoporotics, supplementation with these two nutrients arrested bone loss. It remains to be determined how large a share of the population would benefit from this approach.

Decreased physical activity levels among older persons may contribute to bone loss. Weight-bearing exercise such as walking has been recommended as a preventive strategy. An NIA supported study at the University of Wisconsin has shown that an exercise program was effective in countering bone loss in older women. More studies are needed to assess the long-term benefits which can be expected from exercise.

Research supported by NIA and others has identified other factors, such as age-related changes in bone marrow, several hormones, and nutrients including vitamin K, that could be very important in regard to osteoporosis. It is important to follow these leads, since they could lead to better treatment and prevention alternatives than are currently available.

It has become increasingly recognized that osteoporosis alone is rarely enough to cause hip fractures, which generally occur only after trauma, typically a fall. Studies have identified a subgroup of older persons who fall very frequently. The increased likelihood of these persons to fall is a significant cause of hip fracture which is potentially preventable, and is a medical problem in its own right. Research supported by NIA at the

Albert Einstein College of Medicine in New York has shown that certain older people have specific neuromuscular deficits which severely impair their balance, and which may be treatable. A recent conference organized by NIA identified needs for research on several other visual, neurologic, and cardiovascular problems which may be important causes of falls in the elderly.

Public Education and Prevention Activities of NIA and DHHS:

The NIA has been active in disseminating information on osteoporosis to the general public. We regularly receive both press calls and general requests for information on osteoporosis, its treatment, and prevention. In response to this, the NIA issued an Age Page-- a widely acclaimed, simply written, one page fact sheet called, "Osteoporosis: The Bone Thinner." Over one million copies of these Age Pages were distributed in bulk quantities in supermarkets, in pharmacies, and through the state and area Agencies On Aging, as well as in response to inquiries directed to the Institute. Many small town newspapers and senior citizen newspapers picked up this material and make it available to their readers. Specialized news services such as the NIH News and Feature Service (available here today) and the NIH Search for Health Columns have carried stories on research on osteoporosis.

Recently the Age Page has been revised to reflect a more aggressive approach to the prevention and treatment of osteoporosis. The new Age Page was part of a cooperative effort

between the American Association of Retired Persons (AARP) and the NIA. AARP has made the Age Page as well as more lengthy literature on osteoporosis developed in cooperation with the NIA available to its extensive membership as a part of their Osteoporosis Awareness campaign. AARP has also made their literature available in quantity to this Institute for inclusion in our regular responses to inquiries. The material also appears in the 750,000 copies of Help Yourself To Good Health, a joint publication by the Institute and Pfizer Pharmaceuticals. Information on osteoporosis is also available in NIA's prize-winning publication, "The Menopause Time of Life."

The NIA is encouraged by the efforts of professional and public interest groups such as the American Academy of Orthopedic Surgeons and the newly-organized Osteoporosis Foundation in focusing attention on osteoporosis. We look forward to continuing collaboration with these organizations in stimulating research and public education.

Injury prevention for older Americans has also received attention from the Centers for Disease Control (CDC). CDC recently produced "Prevention of Injury to Older Adults," a selected bibliography providing an overview of the magnitude of injuries among older adults and the types of health education methods and programs being conducted to reduce them. Many environmental hazards have also been identified which cause falls and contribute to the occurrence of hip fractures. The Centers for

Disease Control has funded prevention research focused on falls among the elderly to clarify the role of environmental hazards and to demonstrate the effectiveness of existing prevention methods. This analysis of injuries and the factors of the environment and the victim which contribute to them will increase the effectiveness of prevention efforts.

CDC has also initiated a project with the Dade County, Florida, Department of Public Health to assist the country in designing and conducting an epidemiology population-based study of the elderly to determine the causative factors of nonwork-related injuries. This project will develop, implement, and evaluate a model prevention program designed to reduce the incidence of injuries and their associated costs.

Our efforts to prevent osteoporosis and its consequences coincide well with the Department of Health and Human Services' strategy for our older people, as first stated in the Surgeon General's Report, Healthy People--"The ...goal...must not only be to achieve further increases in longevity, but also to allow each individual to seek independent and rewarding life in old age, unlimited by many health problems that are within his or her capacity to control."

This premise is the basis for our national goal, to improve and enhance the health and well-being of our older citizens--by reducing the average annual number of days of restricted activity

due to acute and chronic conditions by 20 percent, to fewer than 30 days per year for people age 65 and older by 1990.

To implement this, the Department has initiated an interagency effort involving the National Institute on Aging, the Administration on Aging, the Office of Disease Prevention and Health Promotion, the Health Care Financing Administration (HCFA) and other agencies. A principal activity of the Department's Health Promotion for the Elderly initiative is the public education program entitled Healthy Older People, which is addressing issues of nutrition, exercise, use of medications, injury prevention, preventive services and smoking through health promotion messages directed to older people themselves and to the health and social service professionals who serve them.

At the Secretary's request, the governors of almost every State have named agencies to coordinate health promotion activities for older people. Based in the State health department or State office on aging, these lead agencies are working to organize statewide health promotion programs in aging on a continuing basis. As of this date, 31 States have statewide health promotion campaigns underway on behalf of older persons.

To provide support and technical assistance to State and local agencies, the AoA, with assistance from the AoA-PHS Health Promotion Steering Committee, developed a publication distribution plan consisting of more than 30 publications in the

four priority areas of injury control, proper drug use, better nutrition, and improved physical fitness. One document, "A Healthy Old Age: A Source Book for Health Promotion With Older Adults," has already been printed for this initiative. AoA has sent more than 15,000 copies of this publication to State agencies on aging, community and migrant health centers, Indian tribes, service units of the Indian Health Service, and OASIS projects (mini-senior centers located in department stores). Other materials will be distributed as they become available.

A health promotion initiative of this magnitude is a major undertaking and one which the Federal Government cannot conduct alone. We have already been joined by a number of organizations that share our interest in the health needs of older people including the American Association of Retired Persons, the American Hospital Association, and the National Council on Aging.

Directions for the Future:

The state of our knowledge about many of the current and proposed means of preventing and treating osteoporosis is both promising and frustrating. On one hand, we have evidence that they may be helpful in certain persons. On the other, we frequently do not know enough to make well-founded recommendations about their usefulness for specific individuals or groups. This is especially true for the elderly. Data supporting the use of estrogens, calcium supplementation, exercise and other approaches have

mainly come from populations considerably younger than the very elderly persons among whom osteoporosis is most prevalent. It is still unclear which persons in these age groups would benefit from these treatments and what dosages and schedules are best. We very much need better ways of identifying persons at especially high risk of fracture, since these would benefit most from treatment.

These gaps in our knowledge of the effects of hormones, nutrition, and exercise have limited our ability to make more specific recommendations for prevention strategies, as well as our ability to advise individual patients. This is especially frustrating since many of the potentially useful strategies involve nutrition and exercise choices that are readily available to the public. Research in this field has reached a point where it is possible to do the basic studies and clinical trials that would allow us to move from tentative generalizations to specific recommendations. The NIA and the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases are collaborating with leaders in this field to plan a systematic strategy for osteoporosis research to be conducted over the next several years. We believe that this research will help to provide the information which physicians and the public need to choose the best ways of preventing or treating osteoporosis for each individual.

I will be pleased to answer any questions the subcommittee may have.

QUESTIONS FOR DR. T. FRANKLIN WILLIAMS FROM SENATOR GRASSLEY

Question 1: Is it advisable that a younger person who wishes to commence a personal program or routine to prevent osteoporosis consult at the outset a physician who is knowledgeable about this condition?

Answer: A great deal of information about the potential beneficial effects of adequate dietary calcium and vitamin D intake and exercise is available to the public through the efforts of groups such as The Osteoporosis Foundation as well as the public information offices of the NIA and NIADDK. Guidance on maintaining good health, as well as advice on specific measures to protect against osteoporosis, is available through these channels. If an individual has any special problems, such as lactose intolerance, or any particular concerns, then speaking with a physician, registered dietician or qualified nutritionist is advisable. Women in mid-life will need to consult a physician to discuss estrogen replacement therapy at the time of menopause.

Question 2: You cited annual costs associated with hip fractures in the United States of seven billion dollars in 1977, and said that they are certainly higher today.

What is included in this estimate? Does it include the costs of caring for some of those older fracture victims who subsequently have problems needing nursing home care?

Answer: The estimated seven billion dollar annual cost of hip fractures is reported in The Frequency of Occurrence, Impact and Cost of Selected Musculoskeletal Conditions in the United States (Holbrook, Grazier, Kelsey, Stauffer. American Academy of Orthopaedic Surgeons, 1984). The estimate includes the costs of hospital inpatient services, outpatient services (emergency room, diagnostic and theraputic), physician costs (inpatient, outpatient and emergency room), other practitioners' services, medications, nursing home services, insurance and administrative expenses of federally financed programs, and non-health sector goods and services (including transportation to and from appointments with physicians, extra household help, special diets, and alteration to living quarters required by the injury and its sequela).

The estimate does include the costs of nursing home care which are approximately four billion of the seven billion dollars. The analysis of the economic costs of hip fractures indicates that about five billion dollars of the total (nursing home care plus non-health care sector goods and services) results from the disability subsequent hospitalization for the fracture.

Question 3: You mentioned that digestive tract changes among the elderly reduce the ability of older people to absorb calcium. You said also that the typical dietary intake of

calcium in adults in the United States is well below the USDA Recommmended Daily Allowance of 800 milligrams per day.

First, do you know what the actual average calcium intake is for adults in the United States?

Second, what might be the effective daily intake in an older adult with reduced ability to absorb calcium? In other words, how much does this digestive tract problem inhibit the absorption of calcium?

Third, is there anything which can be done to enhance or increase calcium absorption in the older adult?

Answer: The estimated daily calcium intake of adults has been reported by the National Center for Health Statistics in Dietary Intake Source Data: United States 1976-80. The following table presents daily calcium intake by sex and age for adults:

Sex and age		Mean Daily Calcium Intake in Milligrams
Males	18-24 years	1,215
	25-34 years	968
	35-44 years	858
	45-54 years	841
	55-64 years	804
	65-74 years	698
Females	18-24 years	679
	25-34 years	636
	35-44 years	603
	45-54 years	576
	55-64 years	561
	65-74 years	542

The estimated daily intake as shown in the table above is lower for females than for males at all ages, declines with age in both sexes in this cross-sectional survey, and is below both the USDA Recommended Daily Allowance and the recommendations for daily intake made by the NIH Osteoporosis Consensus Development Conference.

The mean or average value does not convey the complete picture however. It is important to note that the variability in calcium intake is quite large. Twenty-five percent of all US women over the age of 45 years are consuming less than 300 milligrams of calcium per day.

At this time, a committee of the National Academy of Sciences is examining the current USDA Recommended Daily Allowances and may present additional or revised recommendations.

It is known that intestinal calcium absorption decreases with advancing age but the magnitude of the decrease is variable

and has been confounded by the several measurement techniques employed. A multiplicity of changes and behaviors conspire to enhance the likelihood of calcium deficiency in older people. These changes and behaviors include a low dietary intake of calcium, inadequate intake of Vitamin D or exposure to sunlight, decreased conversion by the kidney of Vitamin D to its active metabolite which is required for intestinal absorption of calcium, as well as reduced ability of the intestine to absorb. Most experts agree that absorption of calcium is reduced in older people, but it is not possible, given our current state of knowledge, to identify an exact proportional reduction for people of specific age, sex, and health status.

It is recommended that dietary intake of calcium be increased in older people to 1500 milligrams of elemental calcium per day for people not receiving estrogen replacement therapy and 1,000 milligrams per day for people receiving estrogen replacement therapy (estrogen replacement therapy has a calcium sparing effect). There is evidence that the very old may have Vitamin D deficiency, and they should be treated for that deficiency. The Recommended Daily Allowance for Vitamin D is 400 units but the very old may need two to three times that amount. However, higher intakes of Vitamin D may be toxic and must be monitored closely. Simply, if there is clinical evidence of Vitamin D deficiency, it should be treated as one step to increase calcium absorption.

In order for us to make clear and medically sound recommendations for older people with various health problems as well as for those people, young and old, without osteoporosis who wish to prevent the condition, there is a great need for additional research on the dynamics of and influences on calcium intake and absorption.

Question 4: What is the practical upshot of your research on falls going to be? Can we better identify older people who are vulnerable to falls as a consequence of this research? And then, if we can so what--Can we help those people avoid having falls?

Answer: Falls and gait disorders cause pain, fear, suffering, restriction of daily activities, institutionalization and death among older people. The vast majority of the approximately 200,000 hip fractures occurring each year are suffered by elderly people. Many are the result of a fall. The one-year mortality of hip fracture victims probably exceeds 20 percent and only 30 percent return to independent ambulation following hip fracture. Many elderly people are restricted in their activities because of impairments of gait speed or an inability to climb stairs.

Falling and gait disorders are not an inevitable accompaniment of old age. They are the result of diseases and conditions and the interactions of diseases and conditions.

Neurologic, muscular, perceptual and cardiovascular abnormalities are important contributors to falls and gait disorders directly, and through interactions, with psychological and cognitive disorders, architectural barriers and distractions, prescribed and over-the-counter medicine use, and alcohol use.

The NIA has just issued a Request for Applications for investigations of the neurologic, muscular, perceptual and cardiovascular aspects of falls and gait disorders in older people. The goal of this research initiative is to identify the characteristics of people who are the most vulnerable to falling, to classify them by the types of falls they experience, to characterize the specific deficits which distinguish people who fall from those who do not fall, and to elucidate the underlying pathophysiologic mechanisms.

The long range goal of the NIA is to develop the research base for future clinical trials of interventions and specific treatments to prevent falls and gait disorders in older people.

Question 5: One of your charts shows that the prognosis for people after serious hip fractures is not really very good. Why is that? What is it about hip fractures which seems to make it difficult for people to completely recover?

Answer: The reasons for the excess morbidity and mortality following a fracture of the hip are unclear. One study found that pulmonary embolism, acute myocardial infarction and bronchopneumonia were the causes of death in a small series of autopsied patients who had suffered a hip fracture ("Survival and Ambulation following Hip Fracture," C.W. Miller. The Journal of Bone and Joint Surgery. Vol. 60-A, No. 7, October 1978).

We are not certain about the factors and characteristics which make it difficult for people to recover completely but expect that there are several. Immobilization following the injury and the surgery for repair is probably important in contributing to weakness, depression and pneumonia. Hospitalization, in itself, is likely to be contributory because of the risk of contracting an infection while hospitalized. Perhaps most importantly, a hip fracture is an enormous stress for what may often be an already compromised system. There is some evidence that people who do poorly after a hip fracture are more likely to be of very advanced age, to have cognitive or other serious chronic illnesses, and to have experienced functional or mobility problems before the fracture occurred. Because of the great personal and economic costs of hip fracture and the failure of many persons to resume independent living, it is an area which deserves further research attention.

Question 6: The Older Americans Act provides meals to several million older people each year. The average age of participants is somewhere around 70 years.

Can the Older Americans Act meal programs help in this osteoporosis problem?

Answer: Yes. We do not know precisely how much benefit to expect from the Older Americans Act meal programs. However, it is certain that the meal programs do assist in this problem by providing older people with a more balanced and nutritious diet than they might have otherwise.

A representative from the AoA recently contacted the NIA Public Information Office and requested 1,000 copies of the Osteoporosis Age Page for distribution to regional coordinators of nutrition sites. The dietary recommendations found in this Age Page will presumably be used by nutrition site dieticians in planning meals.

It could be extremely helpful if the Older Americans Act meal programs could assure that each meal contained at least the Recommended Daily Allowance of calcium and Vitamin D or perhaps the daily intake of calcium which was proposed by the NIH Osteoporosis Consensus Development Conference.

Question 7: You registered some reservations about the state of our knowledge and our ability to "make well-founded recommendations about their usefulness for specific individuals or groups."

Could you elaborate on that?

Answer: We have accumulated a body of information which suggests the usefulness of calcium supplementation, estrogen therapy, exercise and other approaches for preventing and treating osteoporosis. Much of this information was derived from studies of younger people. Because we do not know the effects of these approaches in older people, we cannot confidently make specific treatment and prevention recommendations for older people.

Physicians must attempt to make recommendations for older people who have other chronic conditions and who are often taking multiple medications. We need further research to answer specific clinically important questions. For example, we need to know what is the best form of estrogen. Is it helpful for women many years past the menopause to begin estrogen replacement therapy? What if there is a family history of endometrial carcinoma? Is it helpful for a 75-year-old woman with advanced osteoporosis to ingest 1,500 milligrams per day of calcium, to increase her sunlight exposure, to take increased amounts of Vitamin D and to begin an exercise program? What form of weight-bearing exercise, if any, should be recommended to an older person with osteoporosis and a slight gait unsteadiness?

Many of the questions which need to be answered can be most appropriately investigated by controlled clinical trials. The

NIA and the NIADDK, in collaboration with noted researchers and clinicians in this area, are planning for a long-range research initiative which will address many of these questions.

QUESTIONS FOR DR. T. FRANKLIN WILLIAMS FROM SENATOR METZENBAUM

We are pleased to learn about the current research projects your agencies are supporting, and the direction of future research efforts.

Question 1: Given the implications of an older population, do you feel that an even more intensive effort is needed?

Answer: Yes. Osteoporosis is a very common condition in older people and often results in vertebral, wrist and hip fractures. Hip fractures are devastating to the individual and often lead to death. There are many promising research leads which may yield clear guidelines for preventing the onset of osteoporosis and for slowing its progression. In view of the demographic changes our country is experiencing and will continue to experience and the prevalence of the condition, it is very important to direct more research effort to osteoporosis.

Question 2: How much is being done to increase awareness in the 20-35 year old population so as to prevent the condition?

Answer: The NIA has written and widely disseminated a fact sheet on osteoporosis. Almost 1,000,000 copies have been printed. The NIA maintains a large and comprehensive press list. Many of these reporters and columnists cover health issues in general, not just those issues of concern to older adults. The introduction to the Age Page on osteoporosis mentions that the disease process may begin at about age 35. This may ensure that reporters who use this material for background view the disease as one which should be brought to the attention of all adults, not just older adults.

Question 3: Would you describe further the skin patch method of administering estrogen? Do you have reservations about this method, or do you believe most problems would be avoided with this method?

Answer: The skin patch method of administering estrogen uses an adhesive patch which is attached to the abdomen. Estrogen is absorbed from the drug reservoir in the patch. Each patch is used for 3 days.

The skin patch has some definite advantages over oral administration. It is almost certainly better and safer. The skin patch method undoubtedly increases patient compliance, delivers the estrogen systemically, and allows the physician to monitor the circulating levels. An important drawback, which will ultimately affect patient acceptance, is monthly menstrual bleeding. Many older women may find this unacceptable.

The skin patch method requires further testing prior to widespread use. More advanced methods may be available in the

future which will eliminate the compliance and intermittent bleeding problems. The most likely development is of a single annual injection which may offer the same apparent protective action for the skeleton.

Question 4: What is the treatment for the neuromuscular deficits impairing the balance of some older people?

Answer: Researchers are attempting to clearly identify and to isolate the many and various neuromuscular deficits which impair the balance of some older people. At this time, the pathophysiologic mechanisms underlying most of the neuromuscular deficits are unknown. Except for instances in which a specific disease that is impairing balance can be identified and treated, for example an inner ear infection leading to dizziness and balance difficulties, our treatments are primarily symptomatic. Mechanical aids such as canes and walkers are often used to help stabilize the older person.

The NIA has issued a Request for Applications to investigate the neurologic, muscular, perceptual and cardiovascular aspects of falls and gait disorders in older people. We hope to stimulate research which will elucidate the neuromuscular deficits and direct us to specific treatment approaches.

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Senator HAWKINS. Thank you, Dr. Williams.

Our purpose here today is to provide a broad record on osteoporosis and how it affects our Nation's men and women. Another purpose is to highlight the existing consensus among the medical community regard to osteoporosis, and we also hope to dispel some myths. It is often said a person's hip breaks and then she falls down. Is that the way it happens?

Dr. WILLIAMS. I think that is probably rarely true, if ever. The best evidence is that falls occur and the bones break with the fall or some other traumatic event. With the very thin bones fracture is very likely in someone with osteoporosis.

Senator HAWKINS. You mentioned several times older women. Everything I read said women over 40.

Dr. WILLIAMS. The incidence of hip fractures begins to rise at age 40. That is quite correct. It goes up exponentially from then on. It is very striking that if one does a graphical plot of hip fractures in this country, there is a distinct rise at age 40, but then from then on the incidence doubles every 6 to 8 years, so that actually half of all hip fractures occurr beyond the age of 75.

Senator HAWKINS. I have been talking to several physicians and rather than complicate people's understanding of what osteoporosis is, since a lot of people are kind of confused by it, I have been told that the simplest remedy, is prevention. At age 40, if all women took six Tums a day, two in the morning, two at noon and two at night, you would get 1,500 units of calcium carbonate. The doctors I know say they keep it themselves on the dashboard of the car and when they go out in the morning they chew up two, at noontime they have two if they have gone for lunch, and then two in the evening. It seems a rather simple solution rather than changing lifestyles, changing diet, which we should do anyway, those that are concerned with health. You have heard that? Is that a simple solution?

Dr. WILLIAMS. Yes, this is recommended by some physicians. Some gastroenterological experts comment that one has to be cautious about the use of calcium carbonate preparations from the point of view that they may cause a rebound acidity in the stomach because one of the effects is to suppress acid in the stomach, and there may be a rebound afterwards. I do not think we know enough yet to have an absolutely clear view on exactly what calcium preparation is the best or what schedule to take it. Certainly that amount of calcium would be desirable and whether Tums is the best answer or some other preparation, still warrants some further investigation, from the points of view of safety and effectiveness.

Senator HAWKINS. What do you do yourself?

Dr. WILLIAMS. I recommend a calcium preparation and I try to be sure my own diet is high in it, but I think any of the preparations that are available on the market are a reasonable thing to take and I think it is well to take them several times a day.

Senator HAWKINS. Do you drink milk?

Dr. WILLIAMS. Yes; I might just add one comment here, that both Dr. Lipsett and I have had a chance to visit in China and we have been impressed with the apparent relatively low amount of osteoporosis in China. That needs further study, and some cross-cultural

studies would be very helpful, but their diet sources of calcium are considerably different from ours, especially bean curd, fish, and green vegetables. They, of course, have a very high level of exercise activity. So I think there are factors that may enter into it that we could learn by some cross cultural studies.

Senator HAWKINS. Exercise is important.

Dr. WILLIAMS. Yes.

Senator HAWKINS. And walking is probably as good as most things we could do.

Dr. WILLIAMS. Great.

Senator HAWKINS. In an era when most people back the car out to get the paper [laughter] in this country, and then we see the results compounding in the Medicare, Medicaid Program, I do not think we can absorb all of these costs in the graying of America.

Dr. WILLIAMS. A half-hour walk every day would be excellent for every person in America.

Senator HAWKINS. I have a duplication of an advertisement that appears in a magazine rather frequently. I have seen it several times myself. Can you see that? It shows a big glass of milk and the ad cites the existence of an osteoporosis detection machine, safe, reliable, it measures bone mass and even projects what could happen to you without preventive treatment. Do you know of a machine that does this?

Dr. WILLIAMS. No; I certainly do not. I know that there will be others on this panel who will be testifying specifically to various objects of the scientific evidence about ways to detect osteoporosis. It certainly is a very important need that we have to be able to have a simple and safe, reasonably inexpensive way to detect the condition earlier, and it is a subject very active in research right now. But we do not have a single answer to that. I do not believe there is any single, simple machine that will do it.

Senator HAWKINS. I would just like to touch briefly on the question of mortality. Our chart indicates that 20 percent mortality can be attributed to hip fractures, and we know that hip fractures are not the cause of death. What are the complications that set in and result in mortality?

Dr. WILLIAMS. As Miss Long mentioned, one of the common problems is pneumonia because a person is laid up in bed, is unable to really function normally and is much more susceptible to infections and other problems, especially in very old people, such a pressure sores which can lead to spreading infection. General nutrition may decline at such time, the circulation is slowed, and there is an increased risk for thrombophlebitis, embolism, almost every complication one can think of. The hazards increase when one has to be maintained in bed or relatively inactive. In addition to the mortality, there is the fact that only about 30 percent of the people who have a hip fracture in the older ages ever regain full ambulatory status. Most have to use walkers or may not be ambulatory at all.

Senator HAWKINS. Thank you very much.

Dr. Lipsett.

Dr. LIPSETT. Madam Chairman, I am Dr. Lipsett, Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, and I personally would like to say it is a pleasure for me

to testify before this committee about osteoporosis. I have already submitted my detailed testimony to you.

Senator HAWKINS. Thank you. We will include that.

Dr. LIPSETT. This year at the House and Senate Appropriations Subcommittees I presented osteoporosis research as a major initiative for our Institute, recognizing all of the problems that Dr. Williams has just described to you and with which you are completely familiar. Research in osteoporosis has long been carried out by NIADDK, and one of the former directors, Dr. Whedon, who is an authority in this area, will be testifying later.

NIADDK has developed a strong intramural program of research in this area that includes world leaders in the study of calcium and vitamin D metabolism. I welcome the opportunity to tell you of our efforts in advancing research on osteoporosis.

To digress for a moment about the information made available to the American people, one year ago NIADDK and the Office of Medical Applications of Research at NIH convened a Consensus Development Conference on Osteoporosis to review and discuss major issues regarding risk factors, prevention, diagnosis, and treatment. I have provided a report for the committee summarizing that conference. Extensive media coverage of the conference, including national television coverage and a large number of magazine and newspaper articles, generated tremendous public awareness of osteoporosis and an outpouring of requests for information; 2 days ago, as it happens, before this meeting we brought together leaders in the field of bone metabolism and hormonal therapy to plan a long-term strategy to deal with the many scientific issues that confront us. I am pleased that two members of that group, Dr. Whedon and Dr. Riggs, will testify today.

Let me first speak to the question of risk factors. We need better and more comprehensive studies of these risk factors. We know of some of them, such as physical inactivity, lack of the estrogen, and calcium deficiency. Our information, however, comes from relatively small studies. Slowly progressive diseases such as osteoporosis are difficult to study. Osteoporosis is difficult to discern at the start of the disease and only becomes apparent after the passage of several years. All of us tend to lose calcium slowly from our bones after age 35, but we are still not clear when and how we can arrive at an early diagnosis of osteoporosis. Certainly, after someone has a typical osteoporotic fracture, there is no diagnostic problem, but we need a better more solid definition of early osteoporosis and the elements that are involved.

Our physical scientists have developed several ways to use radiation to quantify bone mass. We need to support new research, however, so it becomes possible to assess bone mass and its changes safely, routinely, quickly, and inexpensively. Many small tests of therapies have been shown to decrease the rate of bone loss, but because the numbers of patients studied were limited the results are encouraging but not definitive.

It is clear that calcium supplementation and estrogen replacement have a role in prevention, but the roles of other agents in one or another combination need to be worked out. In this regard, NIADDK is currently supporting a large clinical trial on the effects of fluoride and calcium supplementation on osteoporosis. Other

trials are necessary to define further those populations requiring increased calcium, the optimal doses, and to perform ancillary studies.

While these studies proceed, we intend to research on the mechanisms of bone growth and remodeling; these processes become imbalanced in osteoporosis. Basic studies have identified proteins that regulate bone growth.

The efficacy of estrogen therapy after menopause must be explored in depth. There are a series of questions regarding optimal doses of estrogen, the role of other hormones and, in fact, even whether estrogen can be replaced or the risks modulated by the nonestrogen progestins. To reach answers to these questions requires additional knowledge gained from research and large scale clinical trials.

Finally, I would like to say that we are very pleased that a new voluntary health organization, the Osteoporosis Foundation, has been formed to heighten awareness among the public and concerned health professionals concerning prevention of osteoporosis and the importance of research. We at NIADDK look forward to working with the Osteoporosis Foundation and other concerned public and private organizations to combat osteoporosis by building upon the exciting research advances and opportunities in this field and by translating new scientific knowledge into improved clinical practice and prevention efforts.

The collaboration of the National Institute on Aging will allow us to move more quickly in the directions outlined by Dr. Williams. I should be happy to answer any questions you may have.

[The prepared statement of Dr. Lipsett and responses to questions submitted by Senators Metzenbaum and Grassley follow:]

STATEMENT BY

MORTIMER B. LIPSETT, M.D.
DIRECTOR

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES,
AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTES OF HEALTH
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGING
OF THE
COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

JUNE 20, 1985

Mr. Chairman and Members of the Committee:

I am Dr. Mortimer B. Lipsett, Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. I am very pleased to testify before you today about our research efforts to investigate the causes, treatment, and prevention of osteoporosis. For many years, research on osteoporosis and research areas relevant to this disease--such as bone metabolism, nutrition, and endocrinology--has been an important priority of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) and other Institutes of the National Institutes of Health (NIH). Relevant to this, the NIADDK Intramural Program supports a world-renowned group studying calcium and vitamin D metabolism. Previous directors of NIADDK have testified before the House and Senate Appropriations Committees concerning numerous vigorous research efforts that have been focused on osteoporosis. Last year, I presented osteoporosis research as a major initiative to the Appropriation Subcommittees. Dr. Williams, Director of the National Institute on Aging, has just informed you about the widespread prevalence, health burden, and cost of osteoporosis. I welcome the opportunity to bring to the attention of this committee recent research accomplishments and ongoing studies designed to combat osteoporosis.

In April 1984, NIADDK, jointly with the NIH Office of Medical Applications of Research, convened a Consensus Development Conference on Osteoporosis to review and discuss major issues regarding the risk factors, the causes, and the prevention of this important disease. Extensive media coverage of the Conference--including national television coverage and a large number of magazine and newspaper articles--generated tremendous public awareness of

osteoporosis and an outpouring of requests for information. The major findings and recommendations of the Conference are included in this testimony.

What Is Osteoporosis?

Osteoporosis is a condition in which bone mass decreases, causing bones to be unusually susceptible to fracture. Normal bone is in a constant, dynamic turnover of bone formation and bone resorption. In properly nourished young individuals, bones continue to grow and bone mass increases, resulting in a peak bone mass in most people by 35 years of age. The disease process of osteoporosis begins when there is an imbalance in bone turnover in favor of resorption over formation. Bone mass is steadily lost--producing bones that are vulnerable to fracture.

Attaining maximum bone mass may be very important in the prevention of osteoporosis. Many chemical and metabolic factors--as well as factors such as sex, race, and exercise--contribute to building and retaining the adult peak bone mass. White women are at an especially high risk for developing osteoporosis. Peak bone mass is 30 percent higher in men than in women, and 10 percent higher in blacks than in whites. Women are at a further disadvantage because they lose bone mass at a rate of 1.0 percent per year, compared to a bone loss rate of 0.3 percent per year for men.

The two most probable causes of the disease itself are deficiency of estrogen in postmenopausal women and women whose ovaries have been removed surgically, and a deficiency of calcium.

How Is Osteoporosis Diagnosed?

For many people, osteoporosis is not diagnosed until a fracture of the hip, spine, or wrist occurs, and the x-rays reveal decreased bone mass. After other reasons for the loss of bone mass are eliminated, such as medication or other bone diseases, osteoporosis is then diagnosed.

One study investigated the use of x-rays of the spine to determine evidence of osteoporosis before a fracture occurred. In the group of women aged 45-49, 17.9 percent were diagnosed to have osteoporosis; in women over 74 years of age, 89 percent had x-ray evidence of osteoporosis. To fully appreciate the significance of this, it is important to know that there must be a 30 percent loss of bone before the signs of osteoporosis show up on an x-ray. Before the disease can be diagnosed by x-ray, significant bone loss has already occurred. It is a research imperative to develop methods of diagnosis: to enable early identification of bones most vulnerable to fracture, to begin therapies as soon as possible, and to have a measure by which to evaluate the effectiveness of new therapies.

Several non-invasive methods for measuring bone density have been developed. They vary in accuracy, availability, radiation dosage, and cost. A study is under way at the University of Washington to evaluate 6 non-invasive techniques in 50 postmenopausal, osteoporotic women. Two promising techniques use photon radiation to quantify bone mass in the spine and the femur at a low cost, at minimal radiation dosage, and at minimal discomfort to the patient. However, no existing techniques can discriminate adequately early in the disease process between normal and osteoporotic individuals. Bone biopsies

and tissue analyses are also important to eliminate other possible diagnoses and to pinpoint the particular type of osteoporosis present. Bone biopsy has been advanced by the introduction of less traumatic methods for obtaining bone samples and improved tissue preparation techniques. Much work is needed to evaluate and develop techniques for widespread use to measure bone mass safely and at low cost.

What Are the Available Methods of Prevention and Treatment?

At present, there is no reliable method to treat or reverse osteoporosis after it has been diagnosed. Our best hope today is prevention. The Consensus Development conferees stated that, on the basis of current available data, estrogen replacement therapy is the most effective modality for preventing osteoporosis in women. Estrogen reduces bone resorption and halts post-menopausal bone loss. Studies show that estrogen replacement can reduce hip and wrist fractures by 60 percent and also reduce the rate of vertebral fractures.

Another effective preventive measure is sufficient dietary intake of calcium. The usual daily intake of calcium (approximately 500 mg) is well below the Recommended Dietary Allowance of 800 mg, and, in turn, is much less than the intake of 1,500 mg for postmenopausal women, that was recommended by the experts at the Conference.

Adequate levels of vitamin D are needed for optimal calcium absorption. Vitamin D supplements, up to a maximum of twice the daily allowance, are

indicated especially for individuals (such as older persons in nursing homes) who do not receive adequate exposure to sunlight each day.

Moderate weight-bearing exercises, such as walking, were recommended by the conferees as an additional preventive measure.

There are several possible "therapeutic" agents--substances that may be able to promote new bone formation--currently under investigation. These include sodium fluoride, calcitonin, calcitriol, anabolic steroids, and others. Further studies are needed to establish the efficacy of these agents and determine their safety.

Research Efforts of the NIADDK

A major priority of this Institute is to continue research on osteoporosis and make all possible efforts to carry out the recommendations of the Consensus Development Conference. Scientists supported by the NIADDK have focused intensive efforts on several areas in basic and clinical research on osteoporosis: bone metabolism, bone growth factors, the role of vitamin D in bone growth, calcium metabolism, the function of steroid receptors in bone cells, and potentially effective new treatments.

Current studies by NIADDK investigators are looking deeper into the biochemistry and metabolism of normal bone growth and how the processes become imbalanced in osteoporosis. Of important promise are studies of bone remodeling--the dynamic, synchronized process of bone formation and resorption. Many factors play a role in this process including mechanical and

electrical forces, hormones, and local and systemic growth factors. Crucial to further understanding of osteoporosis is fundamental knowledge of mechanisms of bone growth and remodeling and their local and systemic regulation. Recent technological advances in maintaining cell cultures has improved laboratory study of hormonal and cellular interactions. Investigations by NIADDK grantees have led to the discovery of both Human Skeletal Growth Factor, which induces a significant increase in DNA synthesis and increases the growth rate of new bone, and other new skeletal growth factors. A recent application of a previously discovered growth factor, Bone Morphogenic Protein, has promoted new bone formation in patients with head and facial defects. Understanding the normal activity of these and other factors in the bone remodeling process may lead to discoveries of how these factors are altered in osteoporosis.

The NIADDK has a long-standing commitment to foster osteoporosis research. Ongoing studies supported by NIADDK include:

- Investigators at Creighton University are conducting longitudinal studies of 200 women, starting at 35 years of age. Detailed laboratory measurements will establish the profiles of bone change during the pre- and postmenopausal periods. This study and related efforts at Creighton University have established the clinical recommendations of calcium supplementation for those at risk for developing osteoporosis.

- Researchers at the University of Pittsburgh are measuring changes in bone density for postmenopausal women in both exercising and sedentary patient groups. Sophisticated computerized tomography (CT) is used to assess bone

density. The objective of the study is to ascertain and quantify the expected positive influence of exercise on bone structure.

- Investigators at the University of Pennsylvania have developed and are evaluating a new technology for treating osteoporosis. An electric pulse is delivered to the thinning vertebral bones of osteoporotic patients to determine if electric stimulation can induce regeneration of bone. This is a technique that has been proven successful in treating bone fractures.

NIADDK also supports a major clinical trial to study a treatment that may stimulate bone formation. The clinical trial has two centers, the Mayo Clinic and Henry Ford Hospital. Four hundred postmenopausal osteoporotic patients are being enrolled. All patients receive calcium supplementation at a level of 1500 mg daily. The patient population will also include a treatment group receiving 75 mg of sodium fluoride daily and a randomly-selected group receiving a placebo. The purpose is to evaluate in large patient groups the clinical effectiveness of fluoride as an agent to improve osteoporotic bone conditions. Fracture incidence will be determined in both patient groups.

To stimulate research on osteoporosis further, an ad hoc advisory group has been formed to assist the Institute in developing research strategies. Staff members from NIADDK are working closely with our colleagues at the National Institute on Aging to implement a cooperative effort in developing future research projects, as we have done in the past.

The conferees at the NIH Consensus Development Conference made several recommendations concerning areas of basic and clinical research in

osteoporosis which need to be encouraged. These provide special opportunities for research progress and effective application of results to the problem of osteoporosis. The prevailing consensus is that cyclic low-dose estrogen therapy is indicated for women whose ovaries are removed or whose menopause has occurred before age 50. Questions remain concerning the utility, benefits, and risks of hormonal therapy to prevent osteoporosis in elderly women; for women who have had a menopause after 50 years of age; and for non-Caucasian women generally. Studies are also needed to determine the efficacy of the addition of progestins to prevent side effects from estrogen therapy, and to evaluate the risks of long-term estrogen-progestin therapy in postmenopausal women. Small-scale studies have attempted to answer these questions, but long-term clinical trials of various specific patient populations are necessary in numbers large enough to provide valid and reliable estimates of risk, and to determine the optimal regimen to prevent bone loss and fracture. The mechanism of the effect of estrogen in preventing bone loss remains unknown and the possible role of the non-estrogenic progestins must be investigated.

Studies are also needed to define further those populations requiring increased calcium intake, and the optimal dosage and timing for calcium supplementation when necessary. Implementation of these studies will require epidemiologic research to gain more knowledge of populations at risk and major risk factors. This epidemiologic research should lead to large-scale clinical trials.

The panel at the NIH Consensus Conference recommended specifically:

1. Observational and epidemiological studies to determine the impact of multiple demographic and behavioral factors on bone mass and fracture frequency.

2. Clinical studies to determine those factors which predict different responses to intervention.

3. Studies to develop accurate, safe, inexpensive methods for determining the level of risk for osteoporosis in an individual, to establish early diagnosis, and to assess the clinical course of the disease.

4. Studies to develop safe, effective, low-cost strategies which might be applicable to populations at large for maximizing peak bone mass, minimizing bone loss, and preventing fractures.

5. Studies to determine the optimal regimens of gonadal hormones for prevention of bone loss and fracture.

6. Studies on the mechanisms of bone growth and remodeling, regulation, and their alteration in osteoporosis.

7. Studies to understand alterations in the structure and biomechanical properties of bone in osteoporosis.

Conclusion

We have learned much, but not yet enough, about this disease that affects so many in our population. Research efforts in epidemiology, diagnosis, histochemistry, molecular biology, metabolism, and therapeutic applications must be strengthened and expanded to discover the means to treat osteoporosis effectively and to cure it. The NIH, particularly NIADDK and NIA, are committed to pursuing this important research mission.

We are extremely pleased that a new national voluntary health organization, The Osteoporosis Foundation, has been formed to heighten awareness among the public and concerned health professionals regarding prevention and the need for further research. We at the NIADDK look forward to working with The Osteoporosis Foundation and other concerned public and private organizations to combat osteoporosis by building upon the exciting research advances and opportunities in this field, and by translating new scientific knowledge into improved clinical practice and prevention efforts.

Questions from Senator Metzenbaum

TARGETING THE OLDER POPULATION

Senator Metzenbaum: Given the implications of an older population, do you feel that an even more intensive efforts is needed?

Dr. Lipsett: Yes, indeed, a more intensive effort is needed and is being undertaken targeting the older population. Osteoporosis is a major underlying cause of bone fractures in postmenopausal women and older persons in general. Current data point to three probable causes: deficiency of estrogen, deficiency of calcium, and lack of exercise. Rapid bone loss often accompanies menopause; a low calcium intake is common among the elderly in the United States. Current strategies for this population include evaluating estrogen replacement in postmenopausal women; adequate nutrition, particularly calcium intake; and a modest exercise program. The NIADDK has extensive public information activities related to osteoporosis and collaborates with several groups in the private sector including the American Association for Retired Persons.

TARGETING THE 20-35 YEAR OLD POPULATION

Senator Metzenbaum: How much is being done to increase awareness in the 20-35 year old population so as to prevent the condition?

Dr. Lipsett: The NIADDK has extensive public information activities in osteoporosis, including disseminating the conclusion of the Consensus Development Conference on Osteoporosis to the press and broadcast media as well as national voluntary and professional groups in the private sector, patients, Congress, and the general public. The 20-35 year old population is a particularly important one since peak bone mass is achieved at about 35 years of age for cortical bone and earlier for trabecular bone. Special emphasis is being placed on measures that retard or halt the progress of osteoporosis, with particular attention to estrogen and calcium in addition to the role of exercise and nutrition in general. Specifically, one recommendation from the Consensus Development Conference on Osteoporosis of particular importance to this age group is the likehood that an increase in calcium intake to at least 1,000 mg a day beginning well before menopause may reduce the incidence of osteoporosis in postmenopausal women. Data are needed on the efficacy of increased calcium intake in young adult people.

THERAPEUTIC AGENTS FOR NEW BONE FORMATION

Senator Metzenbaum: How far along is the research on possible "therapeutic" agents which might promote new bone formation?

Dr. Lipsett: Several potentially therapeutic agents are currently under investigation. These include sodium fluoride, calcitriol, calcitonin, biphosphonates, anabolic steroids, and ADFR - a complex system of several drugs. Of these, sodium fluoride, and perhaps ADFR and electrical stimulation, seem more promising in their ability to generate new bone

formation. Further studies are needed to establish their usefulness and safety. NIADDK is currently supporting a major cooperative clinical trial at two research centers to evaluate the clinical effectiveness of sodium fluoride to improve osteoporotic bone conditions.

Questions from Senator Grassley

CONSULTING A PHYSICIAN

Senator Grassley: Is it advisable that a younger person who wishes to commence a personal program or routine to prevent osteoporosis consult at the outset a physician who is knowledgeable about this condition?

Dr. Lipsett: Yes, having a physician knowledgeable about one's condition is always advisable. The NIADDK has been striving, through an extensive public information campaign, to ensure that physicians, and indeed patients and the general public, are better informed about osteoporosis, including improved measures for prevention.

HIP FRACTURES

Senator Grassley: One of your charts shows that the prognosis for people after serious hip fractures is not really very good. Why is that? What is it about hip fractures which seems to make it difficult for people to completely recover?

Dr. Lipsett: Approximately 20 percent of the people who suffer a hip fracture die within one year--an even larger percentage of patients are non-ambulatory or need assistance to walk. The high rate of mortality is due to complications from the hip fracture, such as pneumonia that can set in when the patient is under bed rest for extended periods of time. For other patients, who have difficulty recovering from the hip fracture, the healing process may be delayed because of other concomitant medical conditions that commonly affect older persons and prevent them from recovering as quickly as do younger persons.

CONSENSUS DEVELOPMENT CONFERENCE

Senator Grassley: Can you tell us a little bit more about the consensus conferences of the national institutes? Just what are they? What are their purposes? Who participates in them? Do all the institutes hold them? Has this particular consensus conference furnished a research agenda for you?

Dr. Lipsett: The Consensus Development Conference (CDC) Program is designed to improve the lines of communication from the health research community to the practicing physician and the public. Biomedical research scientists, practicing physicians, consumers, and others are brought together in an effort to reach general agreement on whether and how a given medical technology should be used. That technology may be a device, drug, or medical or surgical procedure. A broad-based panel listens to scientific data presented by experts, weighs the information, and then develops a Consensus Statement that addresses the previously prepared series of questions that have been posed to the panel.

Yes, all Institutes can hold them as appropriate and when new evidence emerges. Each CDC is jointly sponsored and administered by one or more of our bureaus, institutes, or divisions at NIH, and by the Office of Medical Applications of Research in the Office of the Director of NIH.

The statement from the Conference on osteoporosis concluded with a section on directions for future research. The panel offered several specific recommendations for studies to be pursued toward a better understanding of osteoporosis, its prevention and treatment.

DIAGNOSTIC TECHNIQUES

Senator Grassley: Can you tell us what some of the key techniques under development are and whether you consider them at this time to be ready for widespread use or just in an early state of development? What is your view of the photon absorptiometry techniques? What is the difference between them? Are they radiation-based techniques, and is there any risk associated with their use?

Dr. Lipsett: During the past 20 years, a number of non-invasive diagnostic techniques have been developed for osteoporosis. They include radiogrammetry (RG) and radiographic photodensitometry (RD), single and dual photon absorptiometry (SPA and DPA), computed tomography (CT), total body calcium by neutron activation analysis (TBC-NAA), and Compton scattering (CS). All these techniques vary in cost, precision, radiation dosage, patient acceptance, ability to measure trabecular-type bone, and ability to measure bone sites most susceptible to osteoporosis.

Dual photon absorptiometry and computed tomography are the most promising techniques because they quantitate bone mass at the spine and the femur, radiation dosage is minimal with DPA (somewhat high in CT), and patient acceptance is generally positive. However, at this time no single technique exists that can differentiate adequately between normal and osteoporotic individuals. Further evaluation and development of these techniques are needed.

BONE MASS

Senator Grassley: You stressed the importance of attaining the maximum bone mass possible, and I believe that others have stressed this in their writing also. What are the most important ages for achieving this? Do we start right at birth, or later in life?

Dr. Lipsett: Osteoporosis is an age-related disorder characterized by decreased bone mass and increased susceptibility to fractures. As I stated earlier, peak bone mass is achieved at about 35 years of age for cortical bone and earlier for trabecular bone. After reaching its peak, bone mass then declines throughout life in all people and is also related to sex, race, menopause, and body weight-for-height ratio. The early years, therefore, may be particularly important for building bone mass through strategies such as adequate calcium intake and effective exercise programs. Bone mass in women decreases rapidly for 3 to 7 years after menopause and in both men and women later in life. A variety of diseases also contribute to bone loss. Reduction in bone mass is the most important reason for the increased frequency of bone fractures in postmenopausal women and in the elderly.

MEAL PROGRAMS

Senator Grassley: The Older Americans Act provides meals to several million older people each year. The average age of participants is somewhere around 70 years. Can the Older Americans Act meal programs help in this osteoporosis problem?

Dr. Lipsett: Although I am not fully informed on the activities of the Older Americans Act meal programs, I am sure that they take care to provide meals based on the recommended daily allowances of important vitamins and minerals. The meal programs would benefit older Americans by ensuring that they are receiving adequate levels of calcium. In determining the adequate level of calcium, the coordinators of these programs might consider that the experts at the Consensus Development Conference on Osteoporosis recommended a daily intake of up to 1,500 mg for postmenopausal women.

Senator HAWKINS. Dr. Lipsett, how many research projects relating to osteoporosis are currently being funded by NIADDK?

Dr. LIPSETT. We currently have between $4 and $5 million per year in osteoporosis research.

Senator HAWKINS. Could you supply the subcommittee for the record with a breakdown of each of the osteoporosis-related research projects you are supporting?

Dr. LIPSETT. I will be happy to do so.

Senator HAWKINS. And the cost of each grant.

Dr. WILLIAMS. I will do the same.

Senator HAWKINS. From each of you, we would appreciate that very much.

Thank you very much for appearing here this morning.

[Information supplied follows:]

In Fiscal Year 1984, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases funded 37 projects in osteoporosis research at a total cost of $4,498,433. This total includes 13 primary projects and 24 secondary projects. A list of each project and its cost in FY 1984 follows.

FISCAL YEAR 1984 NIADDK OSTEOPOROSIS RESEARCH (PRIMARY)

PROJECT	SUB	PRINCIPAL INVESTIGATOR	INSTITUTION	AWARD
2P60AM20557-07	0055	HAWTHORNE, VICTOR M U. of Michigan multipurpose arthritis center-Community component--Epidemiology of osteoarthritis and osteoporosis (human)	UNIVERSITY OF MICHIGAN AT ANN ARBOR	$ 63,520
3R01AM07912-19		HEANEY, ROBERT P Longitudinal study of a pre-osteoporosis population (women)	CREIGHTON UNIVERSITY	$ 145,775
5R01AM21190-06		SANDLER, RIVKA B Life styles and bone densities of postmenopausal women	UNIVERSITY OF PITTSBURGH	$ 192,944
5R01AM27065-05		RIGGS, B LAWRENCE, JR Epidemiology of bone loss, osteoporosis and fractures (human)	MAYO FOUNDATION	$ 158,039
2R01AM27926-04		GENANT, HARRY K Vertebral mineral loss in metabolic bone disease (human)	UNIVERSITY OF CALIFORNIA SAN FRANCISCO	$ 80,151
5R01AM28576-04		RIGGS, B LAWRENCE, JR Fluoride and calcium treatment for osteoporosis (human)	MAYO FOUNDATION	$ 266,771
5R01AM28583-04		KLEEREKOPER, MICHAEL Safety and efficacy of fluoride therapy in osteoporosis (human)	HENRY FORD HOSPITAL	$ 231,365
5R01AM31844-02		JEE, WEBSTER SHEW S Manipulation of bone remodeling in aging (dogs)	UNIVERSITY OF UTAH	$ 161,256
1R01AM33066-01		EDWARDS, W THOMAS Biomechanics of vertebral fracture in osteoporosis (human)	BETH ISRAEL HOSP (BOSTON)	$ 100,399
1R01AM34257-01		LANG, ROBERT New approaches to the treatment of osteoporosis (human)	YALE UNIVERSITY	$ 83,572
5R01AM32526-02		HEATH, HUNTER, III Human calcitonin physiology and bone disease	MAYO FOUNDATION	$ 102,413
5R01AM29792-03		GALLAGHER, J CHRISTOPHER Hormone therapy on postmenopausal bone loss (human)	CREIGHTON UNIVERSITY	$ 62,191
5R01AM32158-02		ARMBRECHT, HARVEY J Changes in calcium and vitamin D metabolism with age (rats)	ST. LOUIS UNIVERSITY	$ 30,462
				$1,678,858

FISCAL YEAR 1984 NIADDK OSTEOPOROSIS RESEARCH (SECONDARY)

PROJECT	SUB	PRINCIPAL INVESTIGATOR	INSTITUTION	AWARD
1R23AM32707-01		FALLON, MICHAEL D Microanalysis of fluid at the osteoclast-bone interface (chicks, rats)	UNIVERSITY OF PENNSYLVANIA	$ 59,400
1R01AM33025-01		TURNER, RUSSELL T Effects of immobilization and suspension on bone (rats, dogs)	MEDICAL UNIVERSITY OF SOUTH CAROLINA	$ 54,652
1R23AM33464-01		CALVO, MONA S Effects of high phosphorus intake on calcium homeostasis (dogs)	MAYO FOUNDATION	$ 42,937
2R01AM34081-02		GLIMCHER, MELVIN J Nature of bone mineral--Inception, maturation, aging (human, cattle, chickens)	CHILDREN'S HOSPITAL (BOSTON)	$ 154,733
5R01AM16061-13		PAK, CHARLES Y Theoretical and therapeutic aspects of calcification (human)	UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS	$ 151,527
1K08AM01244-01		OTT, SUSAN M Bone formation in aluminum toxicity and osteoporosis (human, rats)	UNIVERSITY OF WASHINGTON	$ 54,000
5R01AM11262-18		STERN, PAULA H Effect of hormones on bone resorption in vitro (mice, rats)	NORTHWESTERN UNIVERSITY	$ 169,521
5R01AM15781-13		HAUSSLER, MARK R Function of vitamin D metabolites and bone disease (human,dogs, chickens)	UNIVERSITY OF ARIZONA	$ 67,332
1Z01AM43003-19		AURBACH, G D Mode of action of thyrocalcitonin	NATIONAL INSTITUTES OF HEALTH	$ 172,000
1Z01AM43002-19		AURBACH, G D Structure, secretion and mechanism of action of parathyroid hormone	NATIONAL INSTITUTES OF HEALTH	$ 180,000
1Z01AM43004-19		AURBACH, G D Pseudohypoparathyroidism and related disorders	NATIONAL INSTITUTES OF HEALTH	$ 216,000

FISCAL YEAR 1984 NIADDK OSTEOPOROSIS RESEARCH (SECONDARY)

PROJECT	SUB	PRINCIPAL INVESTIGATOR	INSTITUTION	AWARD
5R01AM16940-12		WOESSNER, J FREDERICK, JR Human cartilage proteases in arthritis (dogs)	UNIVERSITY OF MIAMI	$ 123,736
5R01AM30195-03		GUNJA-SMITH, ZEENAT Collagen and elastin matrix degradation in human disease (also cattle, rabbits)	UNIVERSITY OF MIAMI	$ 99,615
2R01AM19475-10		KENNY, ALEXANDER D Calcium homeostasis--Endocrine and comparative aspects (quail, rats, mice)	TEXAS TECH UNIVERSITY	$ 109,196
5R01AM19675-08		FELDMAN, DAVID Steroid receptors and function in bone cells (rats, mice)	STANFORD UNIVERSITY	$ 149,088
5R01AM32336-02		WEISER, MILTON M Intestinal Ca2+ transport--Vitamin D-dependent mechanisms (rats)	STATE UNIVERSITY OF NEW YORK AT BUFFALO	$ 66,344
5P01AM14881-14	0001	DE LUCA, HECTOR F Metabolism and function of the fat-soluble vitamins -Studies on vitamin D (chicks, rats)	UNIVERSITY OF WISCONSIN MADISON	$ 177,644
5R01AM15888-12		DEFTOS, LEONARD J The calcitropic hormones (human, animals)	UNIVERSITY OF CALIFORNIA SAN DIEGO	$ 170,984
5R01AM18412-08		POSNER, AARON S Ultrastructure of bone mineral (human, rabbits, rats)	HOSPITAL FOR SPECIAL SURGERY	$ 103,423
5R01AM25921-06		PRICE, PAUL A A novel marker for bone turnover (human, rats, rabbits)	UNIVERSITY OF CALIFORNIA SAN DIEGO	$ 93,696
5R01AM28302-03		POSS, ROBERT Non-invasive determination of the properties of bone (sheep)	BRIGHAM AND WOMEN'S HOSPITAL	$ 156,339
2R01AM29789-04		BARON, ROLAND E Role of lymphocytes & macrophages in bone remodeling (mice, rat, rabbits, chicks)	YALE UNIVERSITY	$ 132,766
1R01AM31330-01		GLOWACKI, JULIANNE Regulation of bone resorption (rats)	CHILDREN'S HOSPITAL (BOSTON)	$ 78,694
5R01AM32467-03		MALLUCHE, HARTMUT H Effects of vitamin D metabolites and PTH on bone (dogs, chickens)	UNIVERSITY OF KENTUCKY	$ 35,848
				$2,819,575

Senator HAWKINS. Our next panel will consist of Dr. B. Lawrence Riggs, consultant, Division of Endocrinology and Metabolism of the Mayo Clinic; Dr. Richard Mazess, professor of medical physics, University of Wisconsin; Dr. Luella Klein, past president of the American College of Obstetricians & Gynecologists; and Dr. Donald Whedon, former Director of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, from Tampa.

We will call first on Dr. Riggs.

STATEMENT OF B. LAWRENCE RIGGS, M.D., CONSULTANT, DIVISION OF ENDOCRINOLOGY AND METABOLISM, MAYO CLINIC; RICHARD B. MAZESS, PH.D., PROFESSOR OF MEDICAL PHYSICS, UNIVERSITY OF WISCONSIN; LUELLA KLEIN, M.D., FACOG, PAST PRESIDENT, AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS; AND G. DONALD WHEDON, M.D., FORMER DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Dr. RIGGS. Thank you, Madam Chairman.

I am consultant in medicine at the Mayo Clinic in Rochester, MN, and professor of medicine at the Mayo Medical School. I have been involved in research on osteoporosis and related subjects for the last 20 years.

Osteoporosis has been aptly called the silent epidemic. Bone loss occurs slowly, over many years or decades, as you have heard, without symptoms until a critical threshold is reached, and then multiple fractures begin to occur, but particularly in the spine, the wrist, and the hip. Continued pain, loss of 4 to 8 inches of height, and invalidism are not uncommon outcomes.

It has only been recently that the enormity of the problem of osteoporosis has become clear. At least 1.3 million fractures occurring each year in the United States are because of osteoporosis. Among women over the age of 65, 25 percent will have one or more vertebral stress fractures and by extreme old age one woman in three and one man in six will have had a hip fracture. As you heard, these fractures are very serious with a mortality of at least 15 percent following the fracture and with long-term nursing home care required for 50 percent of the survivors. That is, of course, an enormous cost to the Medicare system.

The direct and indirect costs of osteoporosis have been estimated at at least $4 billion in the United States in 1983. Unfortunately, unless action is initiated now, these figures will become substantially worse because of the progressive aging of the American population. Considering the magnitude of the problem, prevention is the only cost effective approach. It may be too late already to prevent osteoporosis for millions of aging Americans because so much bone has already been lost. Thus, action is needed now by the Congress if this enormous public health problem is to be contained, much less rolled back.

Two major approaches are needed. First, implementation of new information that has been derived from scientific studies to date,

and, second, there should be new research initiatives to further identify the mechanisms of bone loss and develop ways to prevent it.

Osteoporosis is clearly a multifactoral disease with a number of causes, and I think it would be a mistake to think of osteoporosis as only being due to a low calcium intake or only being due to menopause or aging. It is clear there are multiple causes and multiple factors involved.

Although confirmatory data are needed, it seems reasonable to suggest changes in the life pattern of the American public. There is evidence, for example, that a diet low in calcium and high in protein and phosphate will accelerate bone loss. Recent surveys by the U.S. Public Health Service have disclosed that such a diet is commonly consumed by millions of Americans, and, in fact, among middle-aged and older women, the greater group at risk with osteoporosis, the average diet is quite low in calcium.

Insufficient nutrition is particularly evident during the adolescent years when most of the adult bone mass is being laid down, at a time when additional dietary calcium is needed. In other words, one way to attack the problem of osteoporosis is to try to develop a denser skeleton at the time the bone is being formed. But cola drinks which are rich in phosphate have replaced dairy products for many teenagers. For the entire population, excessive use of alcohol and tobacco have shown to be risk factors for bone loss and should be eliminated or reduced, and you heard exercise has been shown to retard bone loss, even among postmenopausal women.

Finally, there is the controversial question of postmenopausal estrogen replacement. If begun at menopause, estrogen can retard bone loss but has certain risks. Although these risks may be less than originally believed, they still are significant, and I believe that estrogen replacement therapy at present should be reserved for those individuals judged to be at greatest risk for osteoporosis.

Obviously we need more information on how best to give estrogen, how to reduce the risk and who is at greatest risk for osteoporosis.

The ability to measure bone mineral density of the spine and hip accurately, and thus to assess risk of fracture, is a major breakthrough in technology. This can be accomplished by using computed tomography or dual photon absorptiometry. This latter method appears to be more accurate and exposes the patient to but minimal radiation. Unfortunately, HCFA, Health Care Finance Administration, has not approved this method for Medicare reimbursement, which I believe to be a very shortsighted policy considering the overall public health costs of osteoporosis.

Finally, as Dr. Williams has mentioned, you do not have to completely prevent osteoporosis to enormously improve the cost savings. If prophylactic measures can retard bone loss for as little as 6 to 8 years, there would be a 50-percent reduction in the rate of hip fractures, which are the most serious of the various fractures due to osteoporosis as well as other fractures and savings that would be well over $1 to $2 billion as a result of that.

[The prepared statement of Dr. Riggs follows:]

Testimony of B. Lawrence Riggs, M.D.
Subcommittee on Aging
Committee on Labor & Human Resources
June 20, 1985

I am a Consultant in Medicine, Mayo Clinic, Rochester, MN and Professor of Medicine, Mayo Medical School. I have been involved in research on osteoporosis and related subjects for the last 20 years and have published over 150 scientific articles on these topics.

Osteoporosis has been aptly called the silent epidemic. Bone loss occurs slowly, over many years or decades and without symptoms, until a critical threshold is reached. Thereafter, recurrent fractures occur in many bones but especially those of the spine, wrist and hip. Continued pain, loss of 4-8 inches of height and invalidism are not uncommon outcomes.

Recently, the enormity of the problem of osteoporosis has become clear. About 1.3 million fractures in the United States each year are attributable to it. Among women over age 65 years, 25% will have one or more vertebral fractures. By extreme old age, 1 women in 3 and 1 man in 6 will have had a hip fracture. These fractures are associated with a mortality of 15% and with long-term domiciliary care in 50% of survivors. Indeed, falls are the leading cause of accidental death in the elderly, primarily because of hip fractures. The direct and indirect costs of osteoporosis have been estimated at $3.8 billion in the United States in 1983.

Unfortunately, unless action is initiated now, these figures will become substantially worse because of the progressive aging of the American population. Considering the magnitude of the problem, prevention is the only cost-effective approach. But it may already be too late for prevention to affect the overall pattern of bone loss for millions of aging Americans.

Thus, action is needed by the congress now if this enormous public health problem is to be contained, much less, rolled back. Two major approaches are needed. First, implementation of new information that has been derived from scientific studies to date. Second, there should be new research initiatives to further identify the mechanisms of bone loss and develop ways to prevent it.

Although confirmatory data are needed, it seems reasonable to recommend certain changes in the life pattern for the American public. There is evidence, for example, that a diet low in calcium and high in protein and phosphate will accelerate bone loss. Recent surveys by the United States Public Health Service, however, have disclosed that such a diet is commonly consumed by millions of Americans. Insufficient nutrition is particularly evident during the adolescent-years when most of adult bone mass is being laid down and at a time when additional dietary calcium is needed. Cola beverages, which are rich in phosphate, have replaced dairy products for many teen-agers. Excessive use of alcohol and tobacco are risk factors for osteoporosis and should be eliminated or reduced. Exercise has been shown to retard bone loss even among postmenopausal women. Finally, there is the controversial question of postmenopausal estrogen replacement. If begun at menopause, estrogen can retard bone loss but has certain risks. Although these risks may be less than originally believed, they still are significant enough that I believe estrogen should be reserved for those individuals judged to be at greatest risk for osteoporosis.

The ability to measure bone mineral density of the spine and hip accurately and, thus, to assess risk of fracture is a major breakthrough in technology. This can be accomplished using computed tomography or dual photon

absorptiometry. The latter method is more accurate and exposes the patient to but minimal radiation. Unfortunately, HCFA (Health Care Finance Administration) has not approved this method for Medicare reimbursement, a very short-sighted policy considering the overall cost of osteoporosis. If prophylatic measures can retard bone loss for as little as 10 years, there would be a 50% reduction in the rate of hip fractures and other fractures due to osteoporosis as well as a savings of over $1 billion yearly and the concomitant alleviation of suffering in millions of older Americans.

Although much has been learned in recent years about the cause and treatment of osteoporosis, there still are major gaps in our understanding. In particular, we need 1) better ways to identify those at greatest risk for future fractures, 2) validation and quantification of risk factors for osteoporosis, 3) better ways to control bone turnover and, thus, retard bone loss and 4) identification of local factors in bone regulating bone growth and the synthesis of them for therapeutic use in osteoporosis. New information of this type may allow the problem of osteoporosis to be brought under control within the next 10 to 15 years.

Senator HAWKINS. You say if you postpone osteoporosis for 6 years you would save 50 percent?

Dr. RIGGS. Look at the poster with the yellow background. You can see that the increase rises very rapidly in late life in women and a little later in men. If you could postpone that rise, and as you see the rise begins around age 75, let us say you could postpone it 6 to 8 years or even a decade. Then you would reach the point where persons will have died from other causes and the problem of hip fracture would be greatly reduced. So I think you do not have to completely prevent osteoporosis. If you can merely retard bone loss, you can resolve a lot of problems.

I have just one last thing to say, if I may, please, and I will be all through. Although much has been learned in recent years about the cause and treatment of osteoporosis, there still are major gaps in our understanding, and I certainly agree entirely with Dr. Lipsett that we must have further research to fill these gaps and particularly we need better ways to identify those at greatest risk for future fractures. Validation and quantification of risk factors for osteoporosis are needed. In other words, not just knowing which risk factors are there, but knowing how important each of the risk factors is, better ways to control bone turnover and thus the rate of bone loss and finally identification of local factors in bone, regulating bone growth and the synthethis and use of these for the therapeutic treatment of osteoporosis.

New information of this type may allow the problem of osteoporosis to be brought under control within the next 10 to 15 years.

Thank you.

Senator HAWKINS. Thank you.

I have some questions for you

Dr. Klein has a plane to catch, but at this moment in time Senator Matsunaga has joined us.

We welcome you. Do you have a statement?

Senator MATSUNAGA. No.

Senator HAWKINS. We appreciate your entrance and your attendance, especially with so many other meetings going on.

At this point we will go to Dr. Klein. I understand you have a plane to catch, and I will take your testimony and ask questions of you and excuse you and then go back to the panel.

Dr. KLEIN. Madam Chairman, members of the subcommittee, my name is Dr. Luella Klein. I am deputy chief of the obstetric service at Grady Memorial Hospital and professor of obstetrics and gynecology at Emory University School of Medicine, both located in Atlanta, GA.

In May, I completed a 1-year term as president of the American College of Obstetricians & Gynecologists, which is the organization representing over 25,000 practicing obstetricians and gynecologists who specialize in women's health care.

I appreciate this opportunity to offer comments on behalf of the American College of Obstetricians and Gynecologists on osteoporosis. I have submitted a written statement and would only like to summarize the statement.

The ACOG supported the recently passed Senate Joint Resolution 61 which designated the week of May 20, 1985, as National Osteoporosis Awareness Week. Since publication last August of our

patient education pamphlet, "Preventing Osteoporosis," we have distributed about 11,000 copies to the public and have sold in bulk over 200,000 copies to physicians, clinics, and hospitals. After I appeared on CBS television last September, within 2 weeks we received requests 3,000 for the pamphlet, "The Menopause Years." These pamphlets are available free of charge to members of the public who contact the college.

ACOG has a task force of obstetricians and gynecologists who are looking at the health care of the aging woman. We heard this morning that osteoporosis is a major public health problem which primarily affects women at the time of menopause and thereafter. Postmenopausal women are at the greatest risk of developing the disease because of estrogen and calcium deficiencies associated with the female aging process. Menopause, marked by the cessation of menstruation, usually occurs around this age. According to the 1980 census, of the 160 million women in the United States, 32 million were 50 years of age or older, and the average life expectancy for women of 50 is an additional 28 years. That is one-third of a woman s lifespan which occurs postmenopausally. As the number of older women increases, the number of women with severe osteoporosis and fractures will increase.

The cessation of menstruation or menopause is a time when ovarian function declines. Each month during a woman's childbearing years, the ovaries produce the hormones estrogen and progesterone, which prepare the uterus to nurture a fertilized egg. As a woman ages, the amount of estrogen and progesterone decreases. The most common symptoms associated with menopause and decrease in circulating estrogen are hot flushes, the sudden sensation of heat that spreads over all parts of the upper body, dryness of the vagina, and skin and hair changes. Estrogen replacement therapy is sometimes given to reduce hot flushes and dryness in the vagina. The use of estrogen to treat skin problems is not recommended because beneficial cosmetic effects of estrogen on the skin have not been established.

During the menopause some women may experience nervousness, irritability, fatigue, or depression. These symptoms are usually not serious. However, for women who experience greater stress associated with their changing bodies and lifestyle, counseling may be recommended.

The use of estrogen to treat these symptoms is not indicated because there is no association between estrogen deprivation and mental performance, mood, or psychological states.

By far the most serious health hazard of menopause is a condition called osteoporosis. Osteoporosis is the loss of bone mass in the aging skeleton which causes the bones to become fragile and more susceptible to fracture. Although the etiology of osteoporosis is unknown, many factors are believed to play a role in its development. Those women who are most at risk for developing osteoporosis include those that we heard about this morning, those who have a small bone structure, are underweight, who lack estrogen after menopause, have a calcium deficiency, do not exercise, are Caucasian or of the Oriental race, smoke, consume large amounts of alcohol, and have a family history of the disease.

There are several things a woman can do to help prevent the onset of osteoporosis. These include modifications in diet and lifestyle and medical intervention. Increased calcium intake before and after the menopause is essential because it protects bone replacement by slowing the rate of bone loss. Before menopause women need about 1,000 milligrams of calcium daily, and the need rises to about 1,500 miligrams per day after the onset of menopause. Major sources of dietary calcium are milk and dairy products, some leafy green vegetables, and seafood. Calcium supplements may be recommended.

Regular weight-bearing exercises, such as walking, aerobic dancing, and cycling, may also slow down the rate of bone loss. The most effective way of slowing bone loss for women who are at risk of developing osteoporosis is estrogen replacement therapy. Over 50 percent of the total amount of bone loss following menopause occurs within the first 7 years of estrogen deficiency. Estrogen replacement therapy is most effective if it is begun shortly after the onset of the menopause with effectiveness continuing for about 5 to 8 years. Estrogen replacement therapy, usually administered orally and in a cyclic pattern, should be given for a convenient period of time such as 3 out of every 4 weeks, for 25 days of each month. For the prevention of osteoporosis, however, about six-tenths of 1 milligram of estrogen appears to be necessary and long-term therapy is required.

As with any drug, the use of estrogen involves risks as well as benefits, and increased risk of cancer in the endometrium, the lining of the uterus, has been observed in women receiving estrogen. Recent studies indicate that the addition of progesterone to estrogen will reduce or eliminate this risk. When evaluating the risks versus the benefits of estrogen therapy, it should be noted that approximately 50,000 women die from osteoporosis and related complications each year. Comparably, there are approximately 3,000 who die annually from endometrial cancer. The patient who is receiving estrogen therapy may substantially reduce her risk of death from endometrial cancer by visiting her physician regularly. Endometrial cancer, if detected early, has the highest cure rate of all gynecological cancers.

During the late 1970's several researchers reported that estrogens were linked to an increase in the rate of breast cancer. These findings have been refuted, and the National Institutes of Health Consensus Development Conference on Osteoporosis concluded that the bulk of evidence indicates that estrogens are not associated with an increase in the risk of breast cancer.

Some side effects of estrogen therapy, however, may occur in some women. These include fluid retention, swelling of the body, irritability, abdominal cramping; and breast tenderness. Women who have had breast cancer or other gynecological cancers, who think they may be pregnant, who have abnormal or irregular vaginal bleeding, or a disorder of blood clotting, should not take estrogens. Some women may not need estrogen replacement therapy because they continue to produce enough estrogen for a considerable period of time after the menopause.

All patients receiving estrogen replacement therapy should be seen by a physician at 6- to 12-month intervals, and during these

examinations blood pressure should be taken, breast and pelvic examinations performed, and the effectiveness of treatment evaluated.

The life expectancy for women has increased dramatically. After the menopause, a major part of a woman's adult life still lies ahead. To get the most out of life, prevention and treatment of osteoporosis is essential. This includes a plan of diet, exercise, and for some women estrogen and progesterone replacement.

I would be pleased to answer any questions.

[The prepared statement of Dr. Klein follows:]

STATEMENT OF

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

on

OSTEOPOROSIS

PRESENTED BY

Luella Klein, M.D., FACOG

before the

Subcommittee on Aging
Committee on Labor and Human Resources
United States Senate

June 20, 1985

Mr. Chairman, members of the Subcommittee, my name is Luella Klein, M.D. I am Deputy Chief of the obstetric service at Grady Memorial Hospital and professor of obstetrics and gynecology at Emory University School of Medicine, both located in Atlanta, Georgia. At Grady Memorial, I serve as Director of the High Risk Maternal and Infant Care Project and the Teen Services Clinic. In May, I completed a one-year term as President of The American College of Obstetricians and Gynecologists (ACOG/The College), an organization representing over 25,000 practicing obstetricians and gynecologists (ob-gyns) who specialize in women's health care. I am a graduate of the University of Iowa and received my M.D. degree from the State University of Iowa College of Medicine.

I appreciate this opportunity to offer comments on behalf of The American College of Obstetricians and Gynecologists on osteoporosis and its prevention and treatment. Osteoporosis is a major public health problem which primarily affects women. The disease, which causes over one million bone fractures and the deaths of 50,000 women each year, results in annual health care expenditures of over $4 billion.[1] Increased public awareness and proper education can alert women to the risks of osteoporosis which can help them modify their lifestyles and receive medical treatment to slow down or prevent the condition.

The College supported Senate Joint Resolution 61, recently passed by the Congress and enacted by President Reagan, which designated the week of May 20, 1985 through May 26, 1985 as "National Osteoporosis Awareness Week." To educate the Congress about the disease and gain support for the resolution, the ACOG distributed copies of our patient education pamphlet, "Preventing Osteoporosis", and our technical bulletin, "Osteoporosis", to all members of the House and Senate. In addition, since publication of the patient education pamphlet last August, the ACOG Resource Center has distributed

over 11,000 copies by request and free of charge to members of the public. Several women's magazines, including Good Housekeeping and Ladies Home Journal, have published excerpts from the pamphlet.

The ACOG column, "Woman's Health", distributed weekly to over 700 newspapers nationwide, was titled "Osteoporosis" for the week of October 22, 1984, and a later column published during the week of January 7, 1985, focused on "Menopause: Another Time of Life". Last September, I appeared on the CBS Morning News to discuss physical changes and what to expect during menopause. We will continue to increase public education efforts in these areas.

My testimony will focus on the link between menopause and osteoporosis as postmenopausal women are at greatest risk of developing the disease due to estrogen and calcium deficiencies associated with the female aging process. State-of-the-art strategies for prevention and treatment of the disease, particularly estrogen replacement therapy (ERT), will be discussed.

According to the 1980 census, of the 116 million women in the United States, 32 million were 50 years of age or older.[2] Menopause, marked by the cessation of menstruation, usually occurs around this age. The average life expectancy of women is 28 years, or one-third the life span, beyond the last menstrual period.[3] In addition to physical changes, many women find that menopause coincides with the beginning of a different phase of life, one in which they may pursue new or different careers, education, and hobbies.

The cessation of menstruation is linked with a decline in ovarian function. Each month during a woman's childbearing years, the ovaries produce the hormones estrogen and progesterone which prepare the uterus to nurture a fertilized egg. As a woman ages, the amount of estrogen gradually decreases but does not entirely diminish since estrogen is produced in small amounts by other glands and in body fat. Post-menopausal women produce little, if any, progesterone.

Changes linked to the menopause often begin several years before they become evident to the individual and continue for several years thereafter. The menopause affects women in various ways. Some women may experience few, if any, symptoms whereas others find their lives disrupted considerably. It is important to note that treatment is available.

The most common symptoms associated with the menopause and decrease in circulating estrogen are hot flushes, dryness in the vagina, and skin and hair changes. Hot flushes are sudden sensations of heat that spread over part or all of the upper body. These sensations occur for a short period and subside. Women who have this symptom can expect it to last for a year or two. Estrogen replacement therapy is sometimes given to relieve hot flushes. Dryness in the vagina as well as itching, and burning, can also be treated with estrogen. Beneficial cosmetic effects of estrogen on the skin have not been established, and the use of estrogen for this purpose is not recommended.

Some women may experience nervousness, irritability, fatigue, insomnia, or mild depression during the menopause. These symptoms are usually not serious, however, and for those women who experience greater stress associated with their changing bodies and lifestyles, counseling may be recommended. The use of estrogen to treat these symptoms is not indicated because there is no association between estrogen deprivation and mental performance, mood, or psychological state.

By far, the most serious health hazard of the menopause is a condition called osteoporosis. Osteoporosis is the loss of bone mass in the aging skeleton which causes the bones to become fragile and more susceptible to fracture. Although the etiology of osteoporosis is unknown, many factors are believed to play a role in its development. Those women who are most at risk for developing osteoporosis include those who have a small bone structure, are

underweight, lack estrogen after menopause, have a calcium deficiency, do not exercise, are of the Caucasian or Oriental race, smoke, consume a large alcohol intake, and have a family history of the disease.[4] Caucasian and oriental females are at greater risk than are white males or blacks of either sex because they have a smaller bone mass.

Bones are composed of calcium and protein. There are two different types of bone in the body, cortical and trabecular, and all bones in the body contain some of each. Cortical bone is found on the outside, and trabecular bone, which is filled with holes, is located on the inside. When the bones lose calcium and protein, they remain the same size, but the walls of the cortical bone become thinner and the holes in the trabecular bone become larger. It is estimated that calcium loss in the bones occurs at the rate of one to two percent a year.[5] These changes in composition greatly weaken the bone.

Several studies indicate that low-dose estrogen therapy can arrest or retard bone loss if treatment is begun shortly after the menopause.[6] Although it is believed that estrogen may play a role in calcium metabolism, the mechanism is not known.[7]

The National Institutes of Health Consensus Development Conference on Osteoporosis held on April 2-4, 1984, reported that osteoporosis may affect between 15 and 20 million Americans.[8] More than 1 million fractures attributable to osteoporosis occur annually in individuals over the age of 45.

The most common sites for bone fractures are the spine, wrist, and hip. Twenty-five percent of women over 60 years of age have documented spinal compression fractures in association with osteoporosis. As many as 50 percent of women will develop vertebral fractures by age 75. In addition, vertebral bones in women can collapse resulting in a "dowager's hump" which can lead to a decrease in height of 2 to 8 inches.[9] After age 45 there is a marked

increase in the incidence of distal forearm fractures. By age 60, there are ten times more forearm fractures in women than in men of comparable age. In the United States, it is estimated that more than 250,000 hip fractures occur in elderly women each year. The risk of hip fractures increases with age and reaches a likelihood of 20 percent by age 90; 80 percent of all hip fractures are found to be related to preexisting osteoporosis. Approximately 16.7 percent of women with hip fractures die within 3 months thereafter.

What can be done to detect, prevent, and treat osteoporosis? Presently, there are no tests to identify which women are at risk for developing osteoporosis. However, there are several ways to determine whether the condition is present. Bone loss can be detected through ordinary radiographs (x-rays) of the vertebral spine or bones of the extremities, but these x-rays are limited to recognition of extreme bone loss. Recently developed absorptiometry techniques including dual photon absorption studies of the body have been limited to academic medical centers although their availability is becoming increasingly widespread. Photon absorptiometry, a noninvasive procedure, is a more precise technique to measure bone loss.

The diagnosis of osteoporosis by a physician should include a medical history and physical examination. Special attention should be given to diet, physical activity, and measurements of height and weight. Laboratory studies include a complete blood count, urinalysis, and serum chemistries, including measurements of total calcium, inorganic phosphate, alkaline phosphatase activity, serum proteins, 25-hydroxyvitamin D, and parathyroid hormone. If the diagnosis of osteoporosis was initially based on radiographic findings, bone mineral density should be measured by absorptiometry.

There are several things a woman can do to help prevent the onset of osteoporosis. These include modifications in diet and lifestyle and medical

intervention. The National Institutes of Health Consensus Development Conference panel concluded that estrogen replacement therapy and increased calcium intake are the mainstays of prevention and management of osteoporosis.[10] The panel also indicated that exercise and nutrition may play an important role as well.[11]

Increased calcium intake before and after the menopause is important for the prevention and management of osteoporosis. Calcium is essential for the function of the nerves and some other body parts. If the amount of calcium in the bloodstream falls below a certain level, calcium will be removed from the bones to supply other bodily needs. Calcium protects bones by slowing the rate of bone loss. Before menopause, women need about 1,000 milligrams of calcium a day. This need rises to 1,500 milligrams after the onset of menopause. The National Institutes of Health Consensus Development Conference panel estimated that the average calcium intake for adults is only 450 to 550 milligrams a day.[12] Major sources of dietary calcium are milk, other dairy products, some leafy green vegetables, nuts, and seafood. Calcium supplements in the form of calcium carbonate are also recommended.

Regular weight-bearing exercise may also slow down the rate of bone loss. Walking, aerobic dancing, and cycling are good forms of weight-bearing exercise.

The most effective way of slowing bone loss for those women who are at risk of developing osteoporosis is estrogen replacement therapy (ERT). Over 50 percent of the total amount of bone loss following the menopause occurs within the first seven years of estrogen deficiency. ERT is most effective if begun shortly after the onset of menopause with effectiveness continuing for at least five to eight years.

Estrogen replacement therapy is usually given in a cyclic fashion, utilizing the lowest dosage compatible with treatment of the symptom (hot flushes, vaginal problems, or osteoporosis). Although initial therapy may require higher dosages, ultimately the physician should try to approach a dose level of 0.3 to 0.625 milligrams. For the prevention of osteoporosis, the use of 0.625 milligrams appears to be necessary at present.

Estrogen, usually administered orally, should be given for a convenient period of time such as three of every four weeks or 25 days of each month. Although estrogen is used to treat hot flushes and vaginal problems on a short-term basis, prevention of osteoporosis appears to require long-term therapy. Sequential addition of a progestin during the last 10 days of estrogen administration is recommended to reduce the risk of development of endometrial cancer, cancer of the lining of the uterus. It is probable, but not definitively established, that progestin therapy may protect against breast cancer. The combined estrogen-progestin program is recommended for women who have had hysterectomies, i.e., the surgical removal of the uterus.

As with any drug, the use of estrogen involves risks as well as benefits. The detrimental effects of estrogen use reported in the literature include association with cancer of the endometrium (lining of the uterus) and breast cancer.[13] An increased risk of cancer of the endometrium has been observed in women receiving estrogen.[14] Recent data indicate that the addition of progesterone to estrogen will reduce or eliminate this risk.[15] When evaluating the risks versus the benefits of estrogen therapy, it should be noted that approximately 50,000 women die from osteoporosis and related complications each year. Comparably, there are approximately 3,000 deaths annually from endometrial cancer.[16] The patient who is receiving estrogen therapy may substantially reduce her risk of death from this disease by visiting her physician

regularly. Endometrial cancer, if detected early, has the highest cure rate of all gynecological cancers.

During the late 1970s, several researchers reported that estrogens were linked to an increase in the rate of breast cancer. These findings have been refuted by recent studies. Gambrell reported that the use of estrogen therapy with the addition of progesterone did not increase the risk of breast cancer and may afford some protection.[17] The National Institutes of Health Consensus Development Conference on Osteoporosis concluded that "The bulk of evidence indicates that estrogens are not associated with an increased risk of breast cancer."[18] A multicenter, case control study -- the Centers for Disease Control Cancer and Steroid Hormone Study -- found no appreciable association between postmenopausal estrogen and breast cancer in 20- to 54-year old women.[19]

Side effects of estrogen therapy may occur in some women. These include fluid retention, swelling of the body, irritability, abdominal cramping, and breast tenderness. Women who have had breast cancer or other gynecological cancers, who think they may be pregnant, have abnormal or irregular vaginal bleeding, or a disorder of blood clotting, should not take estrogens. Some women may not need estrogen replacement therapy because they continue to produce enough estrogen for a considerable period of time following the menopause.

All patients receiving estrogen replacement therapy should be seen by a physician at six- to twelve-month intervals. During these examinations, blood pressure should be taken, breast and pelvic examinations performed, and the effectiveness of treatment evaluated. In addition, periodic mammography should be obtained in every woman after the age of 50.

The life expectancy for women has increased dramatically. After the menopause, a major part of a woman's adult life still lies ahead. To get the

most out of life, slowing the rate of bone loss and preventing the development of osteoporosis is essential. Women who are alerted to the risks of osteoporosis at an early age can begin to make modifications in their health habits which will lead to a healthier older population in the years ahead. I will be pleased to answer any questions.

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Paul C. MacDonald, "Estrogen Plus Progestin in Postmenopausal Women," New England Journal of Medicine, Volume 305, Number 27, December 31, 1981.

[16]American Cancer Society, Facts and Figures, February 1984.

[17]R. Don Gambrell, Robert C. Maier, and Barbara I. Sanders, "Decreased Incidence of Breast Cancer in Postmenopausal Estrogen-Progestogen Users," Obstetrics and Gynecology, Volume 62, Number 4, October 1983.

[18]"Osteoporosis Consensus Development Conference Statement," Volume 5, Number 3, National Institutes of Health, Bethesda, Maryland, April 2-4, 1984.

[19]Phyllis A. Wingo, "Risk of Breast Cancer in Women Using Postmenopausal Estrogens," Abstract, Presented at the Annual Clinical Meeting of The American College of Obstetricians and Gynecologists, May 10, 1983.

Senator HAWKINS. Thank you, Dr. Klein.

Your testimony is most important. There is a lot of confusion, I feel, left over from the cancer linkage in the 1960's and the 1970's, and your written testimony shows that those studies indicate that the link has been refuted as far as a connection to breast cancer. That is really important for women to understand, and I appreciate your coming here today.

You mention in your testimony that the American College has distributed copies of a patient education pamphlet as well as the technical bulletin. Was the technical bulletin made available to physicians also?

Dr. KLEIN. Yes. There is a technical bulletin on estrogen replacement therapy and a technical bulletin on osteoporosis for physicians. Technical bulletins are distributed to all fellows of the college.

Senator HAWKINS. What type of physician do you suggest that women go to for evaluation on whether they have osteoporosis or not?

Dr. KLEIN. I think the problem of evaluation of osteoporosis is very difficult because screening procedures are fairly expensive, and I think that the obstetricians and gynecologists, family physicians, internists, people who are routinely seeing women for their regular health care, are the physicians that seem to me the ones who ought to be conscious of osteoporosis and be talking to women, diagnosing osteoporosis, and hopefully trying to prevent it.

Senator HAWKINS. It seems the more press or publicity we get on this subject, the more interest we have on the part of the public. I think that is one of the great services that the media can provide, to educate the public. Many times the public comes in with a little more information than maybe a busy physician who has been seeing so many people a day for a week or for a year until they have to look up some answers for their patients. In my State, where we have a large percentage of our residents over 65, it is very important that it be caught quickly. Hopefully we will have a lot of citizens like Bernice Long who will be working at age 72 and be productive and want to continue to be working and not be handicapped by having hip fractures and wrist fractures.

Dr. KLEIN. I think it is very important to think about prevention before patients really get elderly. It is very difficult to institute exercise programs and medications for people who are very elderly. I think it is very important early on to establish a healthy lifestyle, to decide whether one is going to take estrogen, whether there are benefits or risks to it. I think it is very important for these things to be done before a patient gets into the older osteoporosis age range.

Senator HAWKINS. Is that not quite difficult, to teach people to do all these things before they feel poorly?

Dr. KLEIN. Yes; but I think women are really becoming more cognizant as the menopause approaches about lifestyle, exercise, diet, and calcium intake. At least my experience has been in the last few years that there is a much greater interest and sensitivity to what one needs to do, comparing post menopausal to premenopausal. I think the most difficult problem is in encouraging older patients to establish changes in lifestyles.

Senator HAWKINS. Essentially if you work in one area and then decide to retire and change your entire lifestyle, come to a new State, start a new lifestyle, new friends, new environment—I am working very closely with a county in Florida who has a wellness center. I like the name. They have a great program where every morning anybody that wants to can report to the mall. There they walk. They have a designated walk inside the mall where it is air-conditioned and they do warmups and it is interesting because they know everybody in the mall. Signs are posted, the lingerie department, that is 1 mile. You walk around and go in the cheese shop and that is 2 miles. On alternate days people that sign up for this walking program are supposed to walk outside. They have a stopwatch and they walk to the park, which is 1 mile, 2 miles, and it is fascinating how the projections are being made on these people in the program versus those not in the program who are at home knitting, or watching television, or becoming very sedentary in their way of life, especially if they have been a very physical person and then come, and sit in a boat, and fish all day. They can hardly get up and move. This is a way they started this idea. I think it is fascinating and it could expand to all populations across the country.

As women become aware that this is something to do at middle age, they should start before middle age. I have a rule that middle age is 10 years older than I am at any point in history.

Dr. KLEIN. The older I get, the older it gets.

Senator HAWKINS. I am always interested in prevention and I have just noticed a great interest in this subject from men who feel they will have to carry their wives if she becomes immobile and cannot take care of him as well as men who also become inactive. So we appreciate your interest in this and if you stay in touch with us on any new developments, we would be happy to provide them to the other Senators and maybe they can provide it in mailings to their constituents. It is of great interest to us who are working on the committee in staying well instead of paying the costs of being sick. The average age is going to be 80. We have to look at some prevention, I think, if we are responsible legislators and we appreciate your being with us today. You are excused. I understand you have a plane to catch.

Do you have any questions, Senator Matsunaga?

Senator MATSUNAGA. Well, if she has a plane to catch, I would let her go.

Dr. KLEIN. Not that soon.

Senator MATSUNAGA. You have outlined the symptoms of osteoporosis in a female. What about the men? What are the prominent symptoms?

Dr. KLEIN. I think fractures occur in men as well as women. The difference is they are less frequent in men than in women.

Senator MATSUNAGA. What is the difference? Will you pull that mike closer.

Dr. KLEIN. I think there is not any difference in the symptomatology. It is simply in men and women that hip fractures are more common in women than in men because women start out with less bone mass. Men lose bone more slowly during the aging process than women. But I do not think there is any difference about the

symptoms between men and women. It is just the difference in the age at which they may occur and the fact that men have fewer fractures and less osteoporosis than women.

Senator MATSUNAGA. I suppose——

Dr. KLEIN. We would not recommend estrogen therapy for men. [Laughter.]

Senator MATSUNAGA. One of the dangers you and I face, being white and Oriental, is osteoporosis. Why is that?

Dr. KLEIN. Well, I do not think that we know. I think family history—my mother died of a hip fracture—is a factor. She died following her second hip fracture, and there is certainly something that seems to be familial; that is, if your mother had a hip fracture, you are more likely to have osteoporosis and be subject to hip fractures yourself.

Senator MATSUNAGA. Dr. Riggs.

Dr. RIGGS. Should I respond, Senator?

I think that blacks clearly have less osteoporosis than Orientals and Caucasians, and part of the reason is that blacks start off with a denser skeleton, so they have thicker bones to begin with. So as they lose bone, they get down to the fracture threshold at a later time and more slowly, and there are perhaps some biochemical and endocrine reasons for that which are presently being studied that may, by explaining why the blacks have relative protection, may help us to be able to treat whites and Orientals.

Senator MATSUNAGA. From my experience, I have noted that whether the mother suffers or the grandmother has suffered hip fractures, some of them, the mother later gets to suffer the same thing.

Dr. KLEIN. That is true.

Senator MATSUNAGA. It appears to me—I do not know what your scientific findings show—that much of this is inherited.

Am I correct in making this assumption?

Dr. KLEIN. Yes, I think you are. I think that osteoporosis seems to be more prevalent in some families, and one of the things that it is important to do when you take care of a woman is to find out whether there has been, in fact, hip fractures, back fractures, or multiple fractures in her mother or grandmother.

Senator MATSUNAGA. Is there any sort of program among physicians to educate their own patients?

Dr. KLEIN. Yes. The American College of Obstetricians & Gynecologists in the last year or so has been developing materials both for members of the college and for their patients, and has been sending both technical bulletins to physicians and patient materials to physicians to distribute to their patients. And our Task Force on Aging I think will come up with a definite program of looking at exercise, diet, estrogen replacement for some women, and healthy lifestyles for women as they grow older.

Senator MATSUNAGA. Thank you very much.

Senator HAWKINS. Thank you for appearing. You may be excused at this time.

Dr. Riggs, I want to thank you for appearing before the subcommittee. I understand you are the president-elect of the American Society of Bone Mineral Research. I compliment you.

I understand that your team at the Mayo Clinic has done some research on the costs associated with osteoporosis. Could you give us a brief outline of that research?

Dr. RIGGS. Yes. We have just looked at the acute health care costs of hip fractures; that is, just the surgical, acute surgical care and the hospitalization and the one to two weeks following. Not the long-term costs.

But it is of interest that these costs extrapolated to the American population indicate that today just acute health costs of hip fractures are $1.5 billion a year. And as I mentioned, our data also show that half of the older Americans that have hip fractures, half of all hip fractures, that this will lead to long-term nursing care costs. So the long-term costs of hip fracture are really enormous.

Senator HAWKINS. You diagnose and treat patients and then track those patients' progress as part of your program at the Mayo Clinic; is that correct?

Dr. RIGGS. Yes.

Senator HAWKINS. Can you describe for the committee the different factors that are considered when making a diagnosis and designing a treatment for the patient?

Dr. RIGGS. Yes. I think enormous progress has been made in not only understanding the causes of osteoporosis but also the magnitude of osteoporosis in recent years. As I mentioned, I have been involved in the treatment and research on osteoporosis for 20 years. And when I first started out, the general consensus among physicians was that osteoporosis was just old age and there was nothing to do, and no one was even treated. I think that all physicians know now that is not the case, although more information to physicians is necessary.

One of the big breakthroughs that has happened in the last 5 years is the ability to measure the density of bone that breaks, whether that be the hip or the spine, and this can be done in one or two ways I mentioned in my testimony. This is very, very helpful because it allows the severity of osteoporosis to be staged in someone who has had a fracture and is provided a means for following up with treatment.

Both calcium and estrogen are effective treatments for most patients with osteoporosis, but unfortunately they do not bring bone back to the normal level. Thus, they are better applied for the prevention of osteoporosis.

What is needed, and what we do not have at the present time, is a means of treatment that will actually make the bone denser.

Now, one such possible form of treatment is sodium chloride, and this is being evaluated on a research basis at our institution and in support hospitals, with support from the NIH, NIA.

Have I answered your question?

Senator HAWKINS. Yes.

I have a bone here that has holes in it. I do not think I have ever seen a bone that is supposedly dense. This is one that has osteoporosis. It has holes all the way through. You can see through it.

Can you see that?

This is the spinal column. Is that typical? Would you look at that and tell me if it is typical?

Dr. RIGGS. Yes, you can see that the bone is porous.

Porosity is where the porosis part of osteoporosis comes from. Osteo meaning bone in Latin.

While this does show what I was saying as early osteoporosis, I believe this is an early example of osteoporosis, and in most patients that we see, in fact, they have more severe osteoporosis than this and the bones get very, very thin. And from the center part of the spine, the spongy part of the bone in the spine, it is possible to lose up to 70 percent or more in osteoporosis.

Senator HAWKINS. I had another question but I am going to go to Dr. Mazess at this time who is professor of medical physics at the University of Wisconsin.

Welcome. We look forward to your testimony.

Dr. MAZESS. Thank you, Senators.

I am Richard Mazess, professor of medical physics at the University of Wisconsin.

I have been involved there for 20 years in working with diagnostic measurements, principally noninvasive bone measurements, and for the past 5 years I have also been president of Lunar Radiation Corp., which has evolved into the largest manufacturers of bone densitometers today.

Noninvasive methods are needed for evaluation of osteoporosis. They are needed for screening and for diagnosis. All the risk factors we have heard about are really risk factors for reducing bone densities, and it is the reduced bone density at the fracture sites which is responsible for the fractures. Nutrition, estrogen, steroids, and a variety of other factors all impinge upon bone densities. If you can measure bone density at the fracture site, you can assess the fracture risk.

In addition, noninvasive methods are needed to examine the course of the disease over time and to examine the efficacy of treatment. And if that treatment is effective, the possible end point for treatment.

Now, there are a variety of methods, and many are experimental. There are three being used clinically. One is single photon absorpiometry which we developed at the University of Wisconsin 20 years ago. This is useful for measuring appendicular bone; that is, the limb bones, or what we call the peripheral skeleton or appendicular skeleton. It is a radioisotope technique using external radioisotopes, and it is a quite accurate and precise technique. It just happens to measure the wrong area because osteoporotic fractures do not occur in the peripheral bone.

More recently techniques have become available to look at the axial skeleton which is, for instance, the spine, the proximal femur, the proximal humerus, and the pelvis. The advantage of these latter techniques is very few false negatives, whereas in appendicular measurements, of whatever type, we have a lot of false negatives or people who turn out to be apparently normal even though they have the disease. The appendicular methods are less useful in osteoporosis than axial measurements.

There is some controversy over this point, and there is some controversy over the relative value of dual photon absorptiometry as there is on the quantitative data derived from computed tomography. I think most people in the field would say that the axial measurements are far superior to the appendicular, however.

The Government has a role with regard to the noninvasive measurements via research. The NIH and NASA have sponsored much of the research that has been done on these methods and also prior to that time the Atomic Energy Commission.

There is also a role for regulation and the NRC and the FDA do regulate these devices. They regulate the use of the devices by physicians and they are doing a very good job in that area.

I guess the third area is reimbursement, and that is taken care of by HCFA. In my opinion, the reimbursement issue is one which is of considerable import right now. Some inadequate methods, such as single photon absorptiometry, are being reimbursed at high levels. Dual photon absorptiometry is not currently being reimbursed, and this has led to some difficulties. Even major clinical institutions are not able to implement this state-of-the-art technology. I have attached for the record editorials from some of the scientific journals explaining the difficulties that they are having with reimbursement, and I have also attached position papers from the American College of Physicians, the American College of Nuclear Physicians, the Society of Nuclear Medicines, and also a statement by an ad hoc group of experts. I feel that HCFA reevaluation of reimbursement is very important to prevent proliferation of bone centers using inadequate methods as well as to allow adequate methods to come into use for diagnosis and monitoring. Thank you.

[The prepared statement of Dr. Mazess and responses to questions submitted by Senators Grassley and Metzenbaum follow:]

Testimony Richard B. Mazess, Ph.D.
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SENATE HEARING ON OSTEOPOROSIS

In order (a) to diagnose the population at risk of developing osteoporotic fracture, (b) to monitor the course of the disease, (c) to monitor treatment, including establishment of efficacy and endpoints, it is necessary to measure bone by noninvasive methods that can be readily repeated over frequent intervals without harm to the patient. Prior to the 1960's methods were not available, except for the grading of radiographs which does not give a good quantitative assessment.

The federal government impacts on diagnostic procedures through: (a) support of fundamental research, (b) FDA and NRC registration and regulation, and (c) reimbursement (HCFA/OHTA)

In the 1960's, with NASA support, methods including single-photon and dual-photon absorptiometry were first developed. Single-photon absortiometry was commercially implemented in the early 1970's and dual-photon absorptiometry was commercially implemented in 1980. There are now five manufacturers of single-photon machines and four of dual-photon machines. Single-photon absorptiometry, because of limitations of the method, can only be applied to areas of the appendicular skeleton principally the radius but also the humerus, the tibia and the os calcis. These

areas do not reflect the osteoporotic process which predominately affects the axial skeleton at sites such as the proximal femur, spine, proximal humerus, and pelvis. Over the past decade it has been shown that measurements specifically at the fracture sites are needed in order to predict fracture risk at each fracture site. Fracture risk is directly proportional to bone density at the fracture site. There is a moderate correlation among bone density measurements at the various fracture sites but the correlation is not high enough to allow extrapolation from one site to another (for example spine versus femur). Alternatively total body measurements can be made, which reflect all of the fracture sites, however measurements at appendicular sites, such as the radius or os calcis, cannot be used in individual cases to predict fracture risk because density at the appendicular sites does not accurately predict density at the fracture sites. Nevertheless the accuracy is sufficient to allow correct classification in at least 50% of cases, and as much as two-thirds of persons with known osteoporosis will be properly classified as osteoporotic from appendicular measurements. However correct classification is not indicative of correct assessment of fracture risk. Therefore the appendicular measurements can only be viewed as screening techniques rather than as diagnostic techniques. There are severe limitations on this screening use due to the fact that 25 to 35% of osteoporotic cases assessed from appendicular sites will be false negatives, that is they will be assessed as normal even though there is significant osteopenia at fracture sites. Even within the group correctly classified as osteoporotic there is not correlation

between appendicular and fracture sites. This could lead to aggressive therapy being instituted where unnecessary or preventative steps being taken where aggressive therapy was actually demanded.

Given these limitations, and given the fact that reimbursement is not generally given for screening techniques in the absence of a specific established diagnostic code, it is inappropriate for reimbursement to be given for single-photon absorptiometry at this time unless definite osteoporosis is present. Single-photon absorptiometry and other measurements of appendicular bone are still useful as an adjunct to measurements at fracture sites. Appendicular measurements are also useful in other diseases, such as renal osteodystrophy and a number of clinical conditions affecting the bones and infants and children. Alternate methods, other than single-photon absorptiometry, at appendicular sites such as radiographic photodensitometry, radiogrametry, ultrasound and Compton-scattering are still experimental, and have not been thoroughly evaluated by clinical testing in a number of laboratories. They cannot be considered for clinical utilization and reimbursement. HCFA, however, has provided such approval in one instance.

In order to measure fracture sites the chief technique available at this time is dual-photon absorptiometry. This involves relatively low dose, low cost and excellent precision and accuracy. The measurement method has been well-validated over the past fifteen years and is in use in between 100 and 200 clinical installations. The technique can be used to measure bone density at all common fracture sites and can also be used for total body

measurement. In addition quantitative computed tomography (QCT) by either single-energy or dual-energy approaches can be used for evaluation of the spine, but not at other sites. At this time computed tomography procedures are reimbursable. Dual-photon absorptiometry has been considered for reimbursement for the past 3 or 4 years but approval has been delayed because of extended OHTA and HCFA reconsideration.

In order to effectively cope with the new technologies that have become available and additional technologies that may become available a faster route of evaluation needs to be established by HCFA and OHTA. so that first class medical institutions, which are establishing state-of-the-art procedures, are not punished (see attached reports A and B from the Society of Nuclear Medicine and the Am. College Nuclear Physicians). These societies and also the American College of Physicians have produced position papers supporting use of dual-photon absorptiometry. (see attachment C). An ad hoc panel of experts in the bone field have proposed to OHTA an approach similar to that of the DRG's in which fixed reimbursement levels would be given for several types of scans (see attachment D). This would provide reimbursement at a sum equivalent to a chest X-ray ($50) for a measurement of peripheral bone. reimbursement at a level twice that ($100) for measurement of axial bone, and reimbursement at a level four times higher ($200) for a total body measurement. The specific method utilized must be FDA approved but need not be evaluated by HCFA. Measurement frequency greater than once per year is not necessary given the slow changes occuring in osteoporosis (except in fluoride

therapy, or immediately post-oophorectomy, in corticosteroid osteopenia). This scheme would effectively preclude abuse of the reimbursement system for diagnosis and monitoring of osteoporosis. It would also prevent the proliferation of centers utilizing ineffective methods.

There also needs to be acceptance by the FDA of bone density data at fracture sites as an indication of efficacy of treatment. Currently the FDA considers fracture be the end-point of clinical efficacy studies, a criterion which requires long-term, large-scale studies. The high costs of such studies inhibits the investigation of new drugs and drug combinations Since density at fracture sites has been shown to directly indicate fracture risk, such measurements should be utilized for FDA clinical trials.

Government support of research on noninvasive bone measurements over the past 25 years has lead to several major developments. Certainly continued research funding in this area is warranted, as well as funding for public education. However research and public education are costly and slow. The major action of government at this time must be to allow utilization of the noninvasive techniques which have already proven so successful in clinical trials of new drugs as well as in clinical practice. Current policies of the FDA and HCFA have (a) led to utilization and even proliferation of inadequate measurement methods (b) inhibited clinical trials with new agents, and (c) inhibited utilization of effective techniques such as dual-photon absorptiometry in clinical practice. These policies must be changed.

QUESTIONS FOR DR. MAZESS FROM SENATOR GRASSLEY

1. LET ME ASK YOUR VIEW OF THE DEGREE OF CONSENSUS UNDERLYING THE CONSENSUS CONFERENCE'S RECOMMENDATIONS WITH PESPECT TO PREVENTION OF OSTEOPOROSIS THROUGH INCREASED CALCIUM INTAKE AND EXERCISE.

DO YOU SUBSCRIBE TO THIS ADVICE OR DO YOU HAVE RESERVATIONS ABOUT IT, AND IF YOU HAVE RESERVATIONS, WHY DO YOU?

2. IS THERE ENOUGH INFORMATION FROM STUDIES TO INDICATE TO CLINICIANS JUST WHAT MEASUREMENTS OF BONE DENSITY IN GIVEN INDIVIDUALS MEANS AND WHAT THEY SHOULD ADVISE PATIENTS AS A CONSEQUENCE OF PARTICULAR BONE DENSITY MEASUREMENTS?

Reply to Questions from Senator Grassley by R.B. Mazess

1. PREVENTION OF OSTEOPOROSIS THROUGH INCREASED CALCIUM AND EXERCISE: There is almost no evidence that either calcium or exercise will increase bone density, or decrease fractures, in the elderly. In fact, the great majority of direct evidence from bone densitometry is negative. At the same time, calcium balance increases with calcium intake suggesting that increased calcium intakes could produce extraskeletal calcification. It has been supposed that calcium and exercise may have a greater influence on younger adults than on the elderly but again the actual evidence from bone densitometry is almost invariably negative. Our own study on 300 normal young Wisconsin females, age 20 to 40 years, showed no significant difference between the sedentary and the highly active nor between high and low calcium intake groups.

Consensus was reached on the so-called value of these factors at the Consensus Conference because of the composition of the committee. The committee in fact noted that evidence for efficacy was scant but advocated calcium and exercise because there was even less evidence that they would be harmful. However such advocacy is bad advice for the public because high calcium intakes can contribute to kidney problems and because sustained exercise programs, whatever their merit, are rarely maintained. The publicity given these factors will obscure the utility of other agents of demonstrable utility in osteoporosis (vitamin D, metabolites, estrogen, sodium fluoride). The eventual failure of calcium and exercise therapy may lead patients to distrust physicians dealing with osteoporosis.

2. MEANING OF BONE DENSITY: In addition to several excellent previous studies, there is now a definitive study by Dr. Melton at Mayo Clinic showing that the bone density at critical fracture sites (spine and proximal femur) is directly related to fracture risk. Each 10% decrease in density, assessed by dual-photon absorptionmetry, increases risk by two to three-fold so that the usual 30% bone loss seen in fracture patients implies a twenty-fold average increase in risk. However, just as not everyone with high blood pressure will have a stroke so not everyone with low density will fracture. About 50% of subjects with low spinal density will have a fracture. Those who fracture have low spinal densities though many (30%) have entirely normal bone, both trabecular and compact, in the appendicular skeleton. Patients must have measurements of bone density at fracture sites to accurately assess both fracture risk and efficacy of treatment. Physicians have only recently begun to be educated to these facts and about the therapies which are available for preventing bone loss and for rapidly restoring bone that has already been lost.

QUESTIONS FOR DR. RICHARD MAZESS: FROM SENATOR METZENBAUM

As I understand it, a diagnostic technique for identifying individuals at risk would be a significant step forward.

1. Can you explain why HCFA has not approved the more accurate method for measuring bone mineral density?

2. Do you believe that a diagnostic assessment for bone density should be part of routine exams?

3. Could the costs be kept within reasonable limits?

4. How much is being done to increase awareness in the 20-35 year old population so as to prevent the condition?

Reply to Questions from Senator Metzenbaum by R.B. Mazess

1. HCFA APPROVAL FOR ADVANCED DIAGNOSTIC METHODS: At least two factors have delayed approval of new diagnostic modalities for osteoporosis. First, HCFA has an adversary attitude toward health providers, pharmaceutical houses, and medical instrument and technology companies which virtually precludes effective assessment of promising approaches to health care. In the case of bone density measurement by dual-photon absorptiometry, which is the most precise and sensitive method available, there has been an inordinate delay despite overwhelming support from the NIH, the scientific and clinical communities and professional societies. A second factor in this delay was due in part to HCFA's failure to solicit expert advice outside of OHTA through mechanisms usually used by other agencies (for example panels selected by the American Institute of Biological Sciences - AIBS - or by FASEB/LSRO). The dependence on inexperienced personnel from OHTA not only causes delays and inefficiency but opens the door for (a) lobbying efforts by proponents of particular technologies and (b) unethical financial solicitations for funds from aides at HCFA.

2&3. ROUTINE BONE DENSITY EXAMS: It would be useful to have routine exams for osteoporosis using bone densitometry, but only if the cost could be kept low. Current medical reimbursement practices greatly inflate actual costs of procedures. This is done, in part, because third-party insurers do not cover all procedures and/or give only partial reimbursement on some. A survey spine scan, taking only 5-minutes, could be done

economically for $30 and a full exam could be done for $75. However, prevailing rates are double this. The usual charge for the now-outmoded forearm bone densitometry is $100. This rapid procedure should cost no more than $25-$30 given the fact that (a) at least two thousand subjects can be measured annually in most practices and (b) the total annualized costs (including labor, space and materials) of owning and operating this equiment is about $30-$40,000. Survey scans of the spine could be done at a similar cost to those of appendicular bone, but with far greater sensitivity. If every woman could have a spine scan prior to menopause and a few years after, it would aid greatly in starting therapy on those at greatest risk of fracture.

4. AWARENESS OF OSTEOPOROSIS: The dairy industry and makers of calcium supplements have greatly increased awareness of osteoporosis among both the premenopausal and post-menopausal groups. However, increased calcium is ineffective with regard to increasing bone density or decreasing fracture and it can be dangerous in sustained high doses (such as those self-administered today by many women). Still, the heightened awareness will make the population alert to early detection, and amenable to viable therapies such as estrogens, vitamin D metabolites, and/or sodium fluoride. Continuation of the calcium myth by physicians,who should be more knowledgeable than the dairy interests and pharmaceutical houses, will be harmful.

Senator HAWKINS. Thank you, Dr. Mazess.

You answered several questions in your testimony. Are you able to describe for the subcommittee some of the other diagnostic methods that are used to diagnose osteoporosis?

Dr. MAZESS. Well, there is a wide variety of methods that have been used.

Senator HAWKINS. Radiogrametry?

Dr. MAZESS. It is one, but it measures compact bone of the appendicular skeleton, and is relatively insensitive. It is mostly used for research purposes rather than for clinical practice. Radiographic photodensitometry is another method that is used on compact bones of the peripheral skeleton. It suffers from the same deficiencies as all the methods which are used in the peripheral skeleton. It is a measurement removed from the fracture site, and is really not predictive of what is going to happen at the key fracture sites.

Moreover, these measurements at the remote sites seem to be relatively insensitive to various forms of therapy and do not seem to change positively, at least with therapies which are known to increase the trabecular bone content in the actual skeleton.

Senator HAWKINS. CAT scanning used?

Dr. MAZESS. CAT scanning is a method used for the bone of the spine. This is perhaps the most sensitive area to measure. However, the single energy CAT technique which is in use today has certain technical limitations, which make it difficult to get very accurate and very precise values. These difficulties notwithstanding, it certainly is one approach to measurement at a fracture zone and can be used successfully for diagnosis.

Senator HAWKINS. I will show you this ad which we have had blown up so you can see it. I think you have seen it before. It is about osteoporosis, hard to swallow, but preventive treatment is not, and it describes a machine, an osteoporosis detection machine and projects what could happen to you without preventive treatment if you are 35 or older. We keep getting 5 years younger. This is 35 years or older that you should be concerned.

Could you comment on this?

Dr. MAZESS. I think that this machine must have an intimate association with an osteoporosis billing machine. There is a franchising operation which is advertising to the effect that they do have a machine which will detect osteoporosis. It is a single photon absorptiometry machine copied from the one which we developed at the University of Wisconsin, and it is the same type of machine which I described as inadequate given the state of the art today in the detection and monitoring of osteoporosis.

Senator HAWKINS. Thank you very much.

Dr. Whedon.

Dr. WHEDON. Senator Hawkins and Senator Matsunaga, I am very pleased to be here to testify before this committee and on a subject which is of such considerable importance to aging and the aged. I have prepared a statement which is being submitted for the record and I shall make a brief oral statement.

I am G. Donald Whedon, M.D., and I am currently consultant on medical research programs for the Shriners Hospitals of North America at their headquarters office in Tampa, FL. And I live in Clearwater Beach, FL.

Senator HAWKINS. Do you walk to work?

Dr. WHEDON. Outdoors in June? [Laughter.]

As you heard earlier, I have been involved in research on bone diseases for many years and was on the staff at the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases for 30 years and its director for the last 19 years.

I think what is more pertinent to this hearing, though, is that I was a member of the panel of the NIH Consensus Development Conference on Osteoporosis which was held in April 1984. My particular involvement in the work of that Consensus Development Conference was to chair the group which dealt with question No. 5: How can osteoporosis be treated and prevented?

In my prepared statement I quoted three paragraphs from the final report of the consensus panel, those dealing with estrogens, calcium and exercise with regard to treatment and prevention. I would like to make the point actually made already by Dr. Riggs, that although there are some new suggested treatments for osteoporosis which have the prospect of restoring, rebuilding the bone back toward normal, the treatment procedures are still unproven and have to be regarded as still in the research category.

The established methods that we have, estrogen and high calcium intake, mainly act to suppress or retard the rate of bone loss, so we are stuck with a situation now that when these treatments are begun we hope to hold bones at the level of mass and strength at which osteoporosis was detected. So, if detection is long delayed, we will perhaps hold the skeleton at that particular mass with high calcium and estrogens, but the skeleton may have reached a point at which it is quite at risk for fractures. This throws the emphasis, then, on the importance of prevention, of taking steps to maintain the strength and mass of the skeleton before it loses so much that it is in trouble.

We have two main ways of doing that now. One is calcium intake and the other is exercise. With regard to calcium intake, the hearing so far has already alluded to the question of changing habits, life habits of food intake. I think we have simply got to push that and not merely in the older age group. We have got to start early. We have got to tell girls particularly, but also boys, that they should not stop drinking milk during their teens and early twenties. They should keep right on with good mineral intake throughout life.

There is a saying in folklore that says, well, after I have gotten through growing, I do not need milk any more. Nothing could be more harmful, I think, for the future of maintaining a healthy skeleton and preventing osteoporosis.

Senator HAWKINS. And we have a lot of milk.

Dr. WHEDON. Of course, doing it all by diet is more difficult the older a patient gets. They do not want to eat as much. They are beginning to watch their weight. They do not want to take too many calories, so supplements do have to be brought in the picture very definitely in older individuals. By older I mean forties and fifties as well as sixties, seventies, and eighties.

Now, with regard to exercise, I have been involved in the past in studies which showed the deleterious effect of immobilization or bedrest over a long period of time, with normal healthy subjects.

Then only 10 years ago our studies with the astronauts in the Skylab flight series showed that astronauts, who are floating around, not bearing any weight, lose calcium from their skeletons just the way normal healthy subjects did in studies 40 years ago by going to bed for several weeks. There are studies on the other side to show the favorable effect of weight bearing exercise. These studies are less striking, not as well controlled, but they at least all point in the same general direction, that is, of at least protecting, if not for certain favoring bone deposition in, the skeleton.

I would not remove running from the type of exercise that could be used but, obviously, the older a person gets, the more at risk he is for trouble if the exercise is too vigorous. So that walking is certainly to be pushed for most of the individuals involved.

I will just close with a couple of other quick points.

The importance of increasing public awareness: I must say that from the number of phone calls I have received over the last two years, the press, the magazine and newspaper writers are certainly hep to osteoporosis; there have been a wealth of generally very good articles in the press about osteoporosis and what ought to be done about it. I think these writers are to be complimented, but they ought to be urged to keep it up. I think it would be important to have a means of reprinting some of these very good popular articles and getting them widely distributed.

Another point of importance is that the current recommended dietary allowance for calcium by the Food and Nutrition Board of the National Research Council is 800 milligrams a day. I think all of the studies now are rather convincing that this is too low a level to think that it would protect the skeleton of 90 percent of the people, which is what a recommended dietary allowance is supposed to do. So, clearly, I think it might be helpful if the committee were to nudge the NRC and the Food and Nutrition Board about reexamining very carefully that calcium allowance figure the next time they work on their recommended dietary allowance levels.

Finally, the importance of research: The only way we are going to really get a true treatment which will restore the strength of bone is by continuing research studies such as Dr. Riggs very nicely detailed for us. But, in the meanwhile, until we develop better treatments and really effective treatments by increased support of research in this area, we have to rely on prevention. Thank you.

[The prepared statement of Dr. Whedon follows:]

Testimony of G. Donald Whedon, M.D.
Subcommittee on Aging
Committee on Labor & Human Resources
U.S. Senate
June 20, 1985

Senator Hawkins and Members of the Sub-Committee:

I am G. Donald Whedon, M.D., Consultant on Medical Research Programs for the Shriners Hospitals of North America, at their Headquarters Office in Tampa, Florida. I have been involved in research on bone diseases for many years and from 1952 to 1982 was on the staff of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases of the NIH, for the last 19 years of that time as Director of that Institute. I was a member of the Panel for the NIH Consensus Development Conference on Osteoporosis held in April, 1984.

My particular involvement in the work of the Consensus Development Panel was to chair the group which dealt with question no. 5: How can osteoporosis be treated and prevented?

In this statement, for emphasis I shall quote just three paragraphs from that part of the Consensus Statement, paragraphs that deal successively with the recommendations on estrogens, diet and activity:

"Estrogen replacement therapy is highly effective for preventing osteoporosis in women. Estrogen reduces bone resorption and retards or halts postmenopausal bone loss. Case-controlled studies have shown a substantial reduction in hip and wrist fractures in women whose estrogen replacement was begun within a few years of menopause. Studies also suggest that estrogen reduces the rate of vertebral fractures. Even when started as late as 6 years after menopause, estrogen prevents further loss of bone mass but does not restore it to premenopausal levels. .....

Cyclic estrogen therapy should be given to women whose ovaries are removed before age 50 in whom there are no specific contraindications. Women who have had a natural menopause also should be considered for cyclic estrogen replacement if they have no contraindications and if they understand the risks and agree to regular medical evaluations."

"The usual daily intake of elemental calcium in the United States, 450 mg to 550 mg, falls well below the National Research Council's (NRC) recommended dietary allowance (RDA) of 800 mg; the RDA is designed to meet the needs of approximately 95 percent or more of the population. Calcium metabolic balance studies indicate a daily requirement of about 1,000 mg of calcium for premenopausal and estrogen-treated women. Postmenopausal women who are not treated with estrogen require about 1,500 mg daily for calcium balance. Therefore, the RDA for calcium is evidently too low, particularly for postmenopausal women and may well be too low in elderly men. In some studies, high dietary calcium suppresses age-related bone loss and reduces the fracture rate in patients with osteoporosis. It seems likely that an increase in calcium intake to 1,000 to 1,500 mg a day beginning well before the menopause will reduce the incidence of osteoporosis in postmenopausal women. Increased calcium intake may prevent age-related bone loss in men as well."

"Inactivity leads to bone loss. Some recent studies suggest that weight-bearing exercise may reduce bone loss. Modest weight-bearing exercise, such as walking, is recommended."

One of my particular points of emphasis is on prevention, as opposed to treatment. Although there are a number of new suggestions for

treatment which may help to rebuild the lost bone characteristic of osteoporosis, they still are not proven to have benefit and must still be classified as in the research category. Established methods of treatment such as estrogens and larger amounts of calcium in the dietary intake mainly act to suppress the rate of bone loss and do relatively little to help restore bone tissue. Hence, we must stress the importance of having or adopting life styles which will help to prevent bone loss while the skeleton is at normal or near-normal mass and strength and therefore relatively resistant to fracture. At the present time we have two best recommendations for prevention, abundant calcium intake and physical, weight-bearing exercise.

As the Panel recommended, by means of milk, (skim milk if one is watching her or his weight), cheese, shellfish, green vegetables and other calcium-containing foods, people in their thirties, particularly women should develop dietary aptitudes that will provide them with at least 1 gram of calcium per day. More, up to 1.5 gm. or so, would be better.

As for exercise, we know well from studies of healthy young men at bed rest, as part of research on convalescence or recovery after illness, that quiet rest in bed for weeks or months leads to substantial thinning of bones, particularly of the leg bones. More recent studies, in which I also took part, of astronauts in the Skylab flights showed that the lack of weight-bearing in space lead to loss of calcium from their bones in much the same way and degree as from the inactivity of confinement to bed. Studies in the opposite direction to test the probable rebuilding or strengthening of bone by exercise have been less striking, but they point in the direction of a favorable, and certainly a protective, effect of

weight-bearing types of exercise such as running and walking. The prescription for help in prevention of bone loss with aging by physical activity, then, is to walk at least, or to run if sufficiently fit, for at least a mile and at least three times a week. Again, as with calcium, more would be better, up to a level - a level below exhaustive effort.

The other major point I would like to make to this Committee, since it is particularly within its area of interest and concern is the need for greater public awareness of osteoporosis and of the fact that measures are now available - the measures I have mentioned - which if followed would lessen the incidence of significant bone loss and thus the risk of fracture. I must say that over the past two years the print media - newspapers and magazines - have been very active in production of articles about osteoporosis. The quality and accuracy has generally been high. The writers should be praised but also encouraged to continue their good work. If a method or resource were available for reproducing the best of these articles and seeing that many copies could be distributed widely, this would be one useful way of increasing public awareness of this serious disorder.

Finally, a point of distinct importance as well. My remarks should not be interpreted to mean that the answers to osteoporosis are all at hand. As others at this hearing have or will indicate, there is a need for simpler, or less expensive, and more reliable methods of diagnosis of osteoporosis in its earliest stages so that measures can be taken to stop progression of the disease. In addition, there is promise in current research efforts to develop treatments to rebuild bone in the earlier phases of osteoporosis. Such research should be encouraged and better

supported. I realize that this is not an Appropriations Sub-Committee hearing for the programs of the National Institutes of Health, but the statement should be made that continuing research into the cellular processes of bone as a living tissue as well as the conduct of clinical studies will bring about a truly effective treatment. Meanwhile, we must stress prevention in dealing effectively at the present time with this serious disease which is most common in the elderly.

GDW/te

Senator HAWKINS. Thank you both very much.

Dr. Riggs, you mentioned the diet sodas, one of the few who mentioned those. I noticed not the epidemic levels, but it is enough to grab your attention of the diet sodas. We are all interested in staying slim, and I think as we get older, it becomes more apparent. But I see among the young people this craze to have a diet drink. And if you read the ingredients on that can, it would just terrify mineral specialists, bone specialists, what that would do to the thinning of the bone, the ingredients in some of these diet sodas.

I see the same kids running, and then I see the same young people get shin splints. Is that what you call it?

Dr. RIGGS. Yes.

Senator HAWKINS. I did not hear about it, and they say it comes from running. While they tell me it is a great thing they have with shin splints, they are drinking a diet soda. It seems to me we are asking for higher statistics. If it says here one-half of the women 55 to 65 have osteoporosis, three out of four 65 or older have osteoporosis, the present people that are 55 and 65, what are your projections, what is going to happen with this generation 30 to 50 now?

Dr. RIGGS. I think it is a real cause for concern. Most of the adult skeleton is laid down during the adolescent growth spurt during the teenage years, and the denser the skeleton is, the more you can lose without losing that critical level where fractures begin to occur.

So one of the best ways to prevent osteoporosis is to encourage ways that would make the skeleton more dense.

It has been in my generation very common for teenagers to drink a large number of milkshakes and so forth. As I point out, that has been largely replaced by cola beverages, and it is the ratio of phosphate and calcium in the diet that seems to be important, the higher the phosphates and the lower the calcium, and that is exactly what I was talking about, drinking cola beverages instead of milk beverages.

Senator HAWKINS. The higher the phosphates——

Dr. RIGGS. It is a ratio of calcium and phosphates. If the phosphates are high without enough calcium, it will cause a decrease in calcium absorption.

Senator HAWKINS. The phosphates are in the diet drinks. It does not say how much.

Dr. RIGGS. That is right.

Senator HAWKINS. So that would help the holes in the bone?

Dr. RIGGS. That is right.

Senator HAWKINS. We have a lot of work to do.

Senator Matsunaga.

Senator MATSUNAGA. I am a man. I am lucky.

Senator HAWKINS. We will see. [Laughter.]

Dr. RIGGS. I have to remind Senator Matsunaga though that one man in six will have a hip fracture if he lives into advanced life, so it something that unfortunately happens to men as well as women.

Senator HAWKINS. It is exaggerated in women because of the estrogen level, as I heard today.

Dr. RIGGS. That is part of it.

Senator HAWKINS. But inactivity must have something to do with it also as we sit at our hearings and sit at our desks and sit in

the car to go home. I have made a list of how much I sit and I have a standup desk canal.

Dr. RIGGS. Very good.

Senator HAWKINS. It may be helpful if we were to send our constituents a questionnaire regarding the modest amount we have learned here this day from you physicians and see if this has really been transposed to our constituents as much as they know about the Social Security. I think they also should understand there is something you can do if you are underage. Maybe we could develop a simple questionnaire, did you know, that type of thing, and send it to our constituents.

We would like to work with you, and I thank you both for coming here.

Senator MATSUNAGA. I have a question.

Senator HAWKINS. Excuse me.

Senator MATSUNAGA. Dr. Whedon, in your statement you said that there is a need for simpler or less expensive, more reliable methods of diagnosis of osteoporosis in its early stages so that measures can be taken to stop progression of the disease. Dr. Mazess is gone, but he mentioned single photon absorptiometry and dual photon absorptiometry.

Do you have any idea, through experience or otherwise, which of these are more effective and what degree of success has there been with either the single or the dual photon absorptiometry?

Dr. WHEDON. Yes; I have had some experience with the single photon absorptiometry method. And Dr. Mazess is quite correct, that this technique applies to the wrist, either the midradius or to the end of the radius toward the wrist and is, therefore, on a peripheral bone, as Dr Mazess described it. He is quite correct in saying that this technique is not really reliable in turning up at any time early osteoporosis of the spine. False negatives, he called it, and that is correct. In other words, one can have a perfectly healthy wrist bone by this technique and have a terrible spine. This is true at least up until the ages of seventies and eighties; not until then will the wrist survey by single photon absorptiometry reliably show a bad wrist that mirrors a bad spine.

On dual photon absorptiometry, with which Dr. Riggs has had a lot of experience, the general feeling is that this is an excellent technique because it can be applied directly to the spine. CAT scanning is also a new technique which can be applied to the spine. Both of these techniques are rather expensive, though. It would be very helpful, I think, to somehow figure out how to reduce the cost of these techniques, because you just cannot expect every person to go into a doctor and be able to afford $200 to $300 for one of these tests and repeat them periodically until the test detects osteoporosis.

I think that physicians in the past were really remiss in their periodic examinations of individuals over 40 or so not to take a simple lateral film of the spine, lateral being a shot from the side, of the lower part of the chest area and of the lumbar area. Now, it is true that this is not a very sensitive detector. There has to be a loss of 15 to 20 percent of the mineral before thinning of the bones will show up. At least it is a relatively inexpensive test that can be done. I certainly hope that it will go out of date and be replaced by

these newer techniques when they can be made more efficient and certainly less expensive.

Senator MATSUNAGA. As you may possibly know, we have an experiment going on in Hawaii at the Kuakini Medical Center, and they have been using single photon absorptiometry of the heel. I am told that it has proven much more successful than use of the wrists and other areas.

Dr. WHEDON. I am familiar with that work, and I have known Dr. John Vogel for a long time. He is the radiologist involved in this study; his data were shown in a poster session of the recent meeting of the American Society of Bone & Mineral Research here in Washington last week. He does seem to see from his data on hundreds and hundreds of individuals, comparing the heel bone measurement with the density in several other peripheral sites, that of all of the peripheral sites. the os calcus is by far the most sensitive, probably because it contains a lot of trabecular type of bone. He has not yet I believe, made comparisons between the os calcus measurements, that is, the heel bone measurements, and the spine, but he is getting into it. He does have the dual photon absorptiometry method which he is beginning to use.

Senator MATSUNAGA. Dr. Riggs, do you have anything to add?

Dr. RIGGS. I will agree with Dr. Whedon and I will also agree with Dr. Mazess that if you want to accurately know the density of the bone that breaks, you probably need to measure that bone. Probably what we are going to need to do is develop criteria so that we can screen the population at large based on those criteria, say a list of 10 questions. If you are 7 out of 10 positive, then that person should be the one that needs to have the dense determination of the spine to determine whether they are at risk for osteoporosis.

Senator MATSUNAGA. I agree with you that early diagnosis is very important so that treatment can begin in time in order to avoid the most serious outcome.

Dr. RIGGS. Yes, indeed.

Senator MATSUNAGA. Do you think Federal expenditures on this would help, or do you think the private sector can take care of it?

Dr. RIGGS. I think the problem is so large it will probably be necessary for some of both.

Senator MATSUNAGA. One more question, Madam Chairman.

I know that the treatment of taking calcium is highly recommended. On the other hand, there are those who suffer from arthritis who are told to avoid calcium. Am I correct in my statement? How would you balance this? With age you have arthritis creeping up on you too.

Dr. WHEDON. I would put it this way, that I would imagine that there are some people, even doctors included, who think that there is some association between calcium intake and the laying down of bone around joints in the condition known as osteoarthritis, but I know of no data that shows any positive association there.

Senator MATSUNAGA. It is not scientifically based then?

Dr. WHEDON. Right. I know of no basis for that idea.

Senator MATSUNAGA. You agree, Dr. Riggs?

Dr. RIGGS. Yes, I do agree. There is a small group of patients that should not take calcium, particularly those who have kidney

stones or have elevated serum calcium, but for the large majority of the population, high calcium is quite safe.

Dr. WHEDON. I agree one should bear in mind the possibility of kidney stone formation, but this is a modest one, and obviously if a patient has a history of kidney stones, especially, he should not go on a very high calcium diet. At the time the doctor prescribes calcium, he ought to make sure that the fluid intake is adequate, that there is plenty of water taken on each day so that the urine volume will be substantial.

Senator MATSUNAGA. Thank you very much.

Senator HAWKINS. Would you, either of you comment on the loss of heel strength in the astronauts? Did I not read there was a loss?

Dr. WHEDON. Well, that is simply that the heel bone was the bone that was measured on the astronauts and no other bones were measured. That was thought to be the best site in which to measure a loss of calcium, in the skeleton as a whole, and three of the nine astronauts in the Skylab Program did show a significant loss of bone density by that technique. They happened to be the same three astronauts who had the greatest loss of calcium by the metabolic method that we used which actually measured the amount of calcium coming out in their urine and stools during those flights.

Senator HAWKINS. Thank you very much.

Our last panel will consist of Dr. William Peck from the Osteoporosis Foundation, and Gloria Kinney from the National Dairy Council.

We will hear first from Dr. Peck.

STATEMENTS OF WILLIAM A. PECK, M.D., PRESIDENT, THE OSTEOPOROSIS FOUNDATION; AND GLORIA G. KINNEY, PH.D., VICE PRESIDENT FOR NUTRITION EDUCATION, NATIONAL DAIRY COUNCIL

Dr. PECK. Senator Hawkins, thank you very much for inviting me.

I am William Peck, Simon professor of medicine at Washington University School of Medicine and physician in chief of the Jewish Hospital of St. Louis.

I am appearing on behalf of the Osteoporosis Foundation, a newly formed, nonprofit foundation, the presidency of which I hold.

I will not reiterate the material in the first part of my statement because you have heard it before. If I may extemporize, I would like to amend the testimony you heard so far. First, it should be emphasized, that although we do have preventive measures, strategies for safe, effective prevention of osteoporosis, applicable to all individuals at risk, is not available. There is no agent which is widely accepted, totally safe and totally effective. Much more work needs to be done.

Second, we have no way of reconstructing the skeleton, once bone has been lost, and there is a tremendous need for additional information. We are talking about an existing population of older people for whom there is really no good management approach.

Third, there is a form of osteoporosis, the kind you have heard about, which is called primary osteoporosis. That is the osteoporosis which is associated with advancing age and is accentuated in

the postmenopausal period of women. There is a form of osteoporosis which is called secondary osteoporosis in which the osteoporosis is associated with the disease such as cancer of the bone, drug use such as cortisone derivatives and so forth. There are many patients who take cortisone derivatives in pharmacological doses for a variety of diseases. The cortisone derivatives are indispensable in managing those diseases, but the physicians and the patients pay a price because, 5 to 10 years later, the patient may will have severe, debilitating osteoporosis and we do not know how these drugs work, we do not know how these diseases affect bone, and there is a great deal of information needed in this area too.

Finally, there is emerging evidence which suggests that osteoporosis of the jaws may be associated with generalized osteoporosis and may be a cause of tooth loss with advancing age, which is another public health hazard, if you will, of this disease.

As Dr. Riggs pointed out, it seems to us that a combination of the Government and private agencies is needed to fight this disease and to develop improved strategies for public education and for research and research training, in the area of osteoporosis. To that end we are pleased to announce the formation of the new nonprofit foundation called the Osteoporosis Foundation, which really has five goals: First, to heighten public awareness of osteoporosis in a coordinated comprehensive and effective way; second, to educate physicians and other health professionals about osteoporosis; third, to establish a resource registry for education and health care in osteoporosis; fourth, to develop strategies to support research and the training of young researchers in osteoporosis; fifth, to support other societies and agencies interested in osteoporosis and metabolic bone disease such as the American Society for Bone & Mineral Research, the Brittle Bone Society, and the Paget's Disease Foundation.

The officials of the new foundation include former Congressman Paul G. Rogers, who is the chairman of the board; myself as president; Dr. Riggs as one of the vice presidents; Paula H. Stern, professor of pharmacology at Northwestern, as a vice president; Dr. Charles Chesnut, who is our treasurer; and Ms. Barbara Warden, executive director of the National Consumers League, who is our secretary, and three other members.

The office and vital statistics of the foundation are in the handout.

We are, as I said, a new foundation. We had our first annual meeting on April 27 of this year, but we have already embarked on the development of educational programs, a newsletter, and a resource for information for the public as well as for physicians. We plan to sponsor a major clinical and scientific conference on osteoporosis in 1986.

We plan to interact extensively with the media, and we are in the process of assessing the current state of funding for research and academic training in the field of osteoporosis and metabolic bone disease. We envisage an extensive fund raising effort, hopefully to channel much of those funds into research and research training.

It is the feeling of everybody who has an interest in this terrible disease that an Osteoporosis Foundation is an idea whose time has come, and we are going to work very hard to make it a success.

Again we thank you for your interest.

[The perpared statement of Dr. Peck follows:]

THE OSTEOPOROSIS FOUNDATION

TESTIMONY OF WILLIAM A. PECK, M.D.
President, THE OSTEOPOROSIS FOUNDATION

On behalf of the officers, board members and staff of The Osteoporosis Foundation, I would like to thank you for inviting us to participate in this hearing.

Certainly, osteoporosis is a major public health problem. Conservative estimates indicate that 10-15 million people in the United States are affected, that osteoporosis causes over one million fractures and more than 30 thousand deaths annually, and that its cost to society is about six billion dollars a year. Public awareness of osteoporosis is very low, in sharp contrast to many other common, serious diseases; the majority of people at risk for osteoporosis have no knowledge of it, because post-menopausal and aging-related bone loss is silent. Furthermore, primary care physicians, those who are in the best position to intervene medically, are inadequately informed. Lack of lay public and professional knowledge must be corrected, since the bone loss that leads to osteoporosis can be prevented in many instances. In addition to educational deficiencies, we are lacking crucial information concerning its causes, diagnosis and treatment.

There is every reason to believe that awareness of osteoporosis is just beginning to rise in the public and professional sectors.

This apparent rise in awareness reflects at least in part, an impact of the NIH-sponsored Consensus Development Conference on Osteoporosis, held in Washington, D.C. April 1-4, 1984, which I chaired. The statement produced by this conference has received wide publicity.

The growing interest this publicity reflects, combined with the long-standing concerns of the scientific community, has given rise recently to formation of The Osteoporosis Foundation, a non-private foundation that has been established to heighten public awareness and knowledge of osteoporosis; to educate physicians and other health professionals about osteoporosis; to establish a resource registry for education and health care; to develop support for research and the training of researchers in metabolic bone disease; and to interact with and support other societies and agencies interested in osteoporosis, such as the American Society for Bone and Mineral Research, the Brittle Bone Society and the Paget's Disease Foundation,

The Osteoporosis Foundation consists of a board of directors, a scientific advisory board, and an executive director.

Foundation officials include former Congressman Paul G. Rogers, chairman of the board; William A. Peck, M.D., president; B. Lawrence Riggs, M.D. and Paula H. Stern, Ph.D., vice presidents; Charles H. Chesnut, III, M.D., treasurer; Ms. Barbara Warden, secretary; and members Norman H. Bell, M.D., Robert Lindsay, M.D. and John H. Renner, M.D.

The present office of The Osteoporosis Foundation is Suite 510, 612 N. Michigan Avenue, Chicago, Illinois 60611. The telephone number is (312) 751-2248. Mr. John Wright serves as acting executive director.

The foundation is now developing educational, registry, and scientific support strategies and undertaking to acquire funds to pursue its goals. Educational strategies will involve, among others, the development of descriptive brochures and a newsletter concerning osteoporosis suitable for lay and professional interpretation, and a lay and professional speaker's bureau. We will sponsor a major clinical and scientific conference on osteoporosis in 1986, and are planning several major public fund-raising events.

Awareness strategies will include the use of media (radio, television, and the print media), special activities (e.g. senior olympics, golf tournaments), and programs arranged in association with a variety of organizations, such as the American Association of Retired Persons, National Consumers League, Gray Panthers, and many others. Eminent spokespersons will be approached in order to direct public attention to osteoporosis. It is possible to foster the formation of regional and local chapters and activities that will relate to the parent national foundation.

The foundation will assess the current state of funding for research and academic training in the field of osteoporosis and metabolic bone disease, pinpoint areas of need, and undertake to obtain and allocate necessary support under the auspices of its board of scientific advisors.

Clearly, development of an Osteoporosis Foundation is an idea whose time has come. A unique opportunity for public service

exists because of the emerging interest in osteoporosis, and the presence of a large population at risk that is not receiving appropriate educational and medical advice, despite the existence of preventive approaches. We are conviced The Osteoporosis Foundation will play the leadership role in making this happen.

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Senator HAWKINS. Thank you.

You have plans for educating physicians?

Dr. PECK. Yes.

Senator HAWKINS. What are those plans?

Dr. PECK. Specifically we are developing newsletter materials which will be distributed widely through various physician organizations, hospitals and so forth. As you may know, most hospitals in the United States, accredited hospitals, have in-house educational programs. And there is usually a physician who is dedicated or directed to be the director of education for that hospital. We plan to develop a registry of those individuals and, through those individuals, distribute our printed material, visual material, and provide access to our speakers' bureau which is now being developed.

Senator HAWKINS. Is research a top priority for your foundation?

Dr. PECK. I would say that education and research go hand in hand at the top. I am a researcher and I have a natural bias toward research. But as a clinician, I see a tremendous need. There have been advances in public education and health professional education which began before the Consensus Development Conference in April 1984. But since the conference, there has been a dramatic increase. But even with that, I think we are far short of the kind of education that is needed and, indeed, the kind of research that is needed.

Senator HAWKINS. Is nutrition one of the tools for education?

Dr. PECK. Yes. The Consensus Development Panel recommended alterations in our attitudes toward calcium intake and general nutrition. And I think both of these are very important for bone health and will be included in our general educational thrusts.

Senator HAWKINS. Dr. Riggs testified that 50 percent of those who survive a hip fracture require nursing home care.

Dr. PECK. That is correct.

Senator HAWKINS. Do you have any figures yet on your foundation research when a woman breaks her hip how expensive it can get?

Dr. PECK. We do not yet, but we plan to acquire those data. I think Dr. Riggs' figures are absolutely accurate from my clinical experience. I serve on the board of a skilled nursing facility in St. Louis.

Senator HAWKINS. Anybody in your family?

Dr. PECK. No; but I have a group of young daughters so I am very concerned about the possibility that they may develop osteoporosis in the future.

Senator HAWKINS. Do you have any questions?

Senator MATSUNAGA. Yes, Madam Chairman.

I have always felt, and I strongly believe, that the greatness of any society can be measured by the degree to which we care for the elderly, and I feel that there is a great opportunity here to come to the aid of the aged who perhaps do not even realize that they are in need of help.

I congratulate you for organizing the Osteoporosis Foundation.

One of the areas I think you can work very profitably in is at the senior centers. One of my proudest achievements as a legislator here on the Hill, and I have been here for 23 years now, is being the cosponsor of legislation which created the Administration on

Aging. We established senior centers over in Hawaii. I feel so good when I go there now because some of my older friends who used to just sit on the porch literally and rock in the rocking chair now are learning the hula, learning how to live, and dance. They have ballroom dancing, too, and many of them have never danced before in their lives, and now at age 65 or 70, they are learning to dance. And they look so much better. They are healthier. They look younger.

There is an old Oriental adage which my father always used to preach to me, and that is that the soul completely immersed in one's work reflects a youthful face. When he was 82, people used to guess his age to be 62. They used to ask him what his secret was, and he used to recite that maxim. When I was a youngster, he always used to say, "Son, if you want to look young as I do now, work, work, work, and no matter what you do, if you are a ditch digger, you be the best ditch digger, and if you are a doctor, be the best doctor because the only way you are going to be the best to work, work, work. Then, son, you will never grow old."

Well, fortunately, I may have inherited some of his genes in addition to conforming to his teachings. [Laughter.]

He had jet black hair until late in his life. He died at 84, and at age 82 he was a judo instructor and flipped me over. I inherited some of his genes. I have black hair. I do not dye my hair. I am older than you are, Dr. Peck. [Laughter.]

I will be 69 in a few months.

Dr. PECK. I was going to say, Senator, I did not know how old you were, but I am sure you are younger than you really are.

Senator MATSUNAGA. Anyhow, I congratulate you.

Dr. PECK. I would like to extend your comment about the senior centers. We have at Washington University in St. Louis a program which I know you are familiar with. It is called Oasis, Older Adult Service and Information System which is sponsored partly by the Administration on Aging and partly by the May Co., and this is a program of education and recreation for older adults and the programs are held within the May Co. stores. Actually it is now available in Washington through the Hecht Co., and there are three other cities involved. We are now providing the educational materials for the Oasis members. There are 15,000 participants in Oasis in St. Louis, and ultimately this program is targeted for many cities nationally.

I know that Frank Williams, for example, has been very supportive of this undertaking.

Senator MATSUNAGA. So you can make videotapes to be sent to the senior centers on charts like this with a doctor explaining things, and I think it will go a long way toward early diagnosis and treatment. Thank you.

Dr. PECK. Thank you.

Senator HAWKINS. Thank you.

Dr. Kinney, welcome.

Dr. KINNEY. Thank you.

Senators Hawkins and Matsunaga, I am Gloria Kinney. I am the vice president for nutrition education, National Dairy Council in Rosemont, IL, and I really appreciate the opportunity to be here with you today to provide you with some information about our nu-

trition education programs and or nutrition research programs that are related to calcium, bone health, and osteoporosis.

I have submitted written testimony, and summarize here just its highlights. With the written testimony are 22 attachments which provide some of the educational material that we have been developing and disseminating to the American public. These materials should be looked on as an integral part of our testimony.

First of all, I would like to say just a word about the National Dairy Council. It was established in 1915 as an educational-scientific organization on the advice of Dr. E.V. McCullom of the University of Wisconsin. After Dr. McCullom discovered vitamin A in milk fat, he recommended that the dairy industry, as a public service, educate the American public about the health protective values of the nutrients in milk and dairy foods. National Dairy Council was established by the dairy industry on that historic advice, and for the last 70 years it has been providing nutrition education services to the American public.

Early in the 1920's it was recognized that American education is also a grassroots, community-based function. And so over the years the dairy industry has organized and supported local dairy council units affiliated with the National Dairy Council to carry out our nutrition education programming at the local, State, and regional levels. It was also recognized in those early years that no single food or food group contains all of the nutrients essential for health. Thus, the nutrition education programs of the dairy council were based on teaching the American public the importance of eating in moderation a wide variety of foods selected from the major food groups as the foundation of a healthy diet.

Today there are 33 affiliated dairy council units with offices in 126 locations across the Nation. Approximately 250 staff members with professional backgrounds in either dietetics or home economics carry this message to the American public. As special needs or circumstances arise, such as the current public health concern related to osteoporosis, dairy council's educational network can be mobilized to deliver important messages related to nutrition, health promotion, and disease prevention to the general public.

Over the last 2 years, the primary focus of dairy council's educational programming has been on the calcium needs and deficiencies in the American diet and on the prevalence and prevention of the bone disease, osteoporosis. We have accelerated dairy council's involvement and delivery of educational materials and programs on osteoporosis, both to health care professionals as well as to consumers. We have stepped up our research on calcium's role in the development and maintenance of bone health and on calcium requirements at various ages and stages in life.

Since last November, we have been greatly assisted in these nutrition education and research endeavors by additional funding provided by the National Dairy Promotion & Research Board of Arlington, VA. This board was established by an act of Congress to develop a coordinated program of promotion designed to strengthen the dairy industry's position in the marketplace and to maintain and expand domestic and foreign markets and uses for fluid milk and dairy products.

At this time I would like to highlight some of the specific activities that we have undertaken to increase awareness of osteoporosis and to provide information to the public and to health professionals.

First of all, we disseminated the reference manual to health professionals called "Calcium: A Research Summary for the Health Professional." This resource provides up-to-date information on all aspects of osteoporosis and has been provided to approximately 67,000 health professionals across the country.

We have developed eight client and consumer information brochures on various aspects of calcium, bone health, and osteoporosis and have made them available to consumers through health professionals as well as through other channels. To date, approximately 7.5 million pieces of these consumer education materials have been distributed.

We are conducting exhibits on calcium and bone health at 12 national conventions of health professionals to alert them to the dangers of osteoporosis and to changes in lifestyle that will prevent or at least delay its development. These exhibits will have an outreach to 100,000 health professionals during this next year.

Advertisements have been placed in professional journals to create awareness of the Dairy Council's educational materials and services, and our estimated outreach here is to approximately 600,000 health and education professionals through their professional journals.

We have also placed consumer exhibits in such places as airports, shopping malls, health fairs, and office building lobbies to provide information and hand out literature on osteoporosis and bone health. It is difficult to estimate accurately how many people have see these exhibits, but we know it is upwards of 2 million.

We have developed a slide-tape presentation called "Osteoporosis and You." This presentation, which is aimed primarily at women, relates the importance of a calcium-rich diet and physical activity in the prevention of osteoporosis. Volunteer speakers, trained by Dairy Council, have presented "Osteoporosis and You" to an estimate 175,000 consumers over the last 6- to 8-month period.

We have developed periodical literature. We have a regular publication called Dairy Council Digest, which is directed to nutrition scientists and health professionals. Recent issues of this digest as well as of Nutrition News, a quarterly publication directed to health education professionals, have been devoted to calcium, bone health, and osteoporosis. Together these publications reach about 180,000 health professionals across the country.

We have developed a 15-minute film on osteoporosis. The film features two physicians, one a researcher on bone disease and the other a practicing obstetrician/gynecologist. So far, 168 copies of this film have been placed in Dairy Council's lending libraries across the country so that health professionals may use them with adult consumers and/or clients with whom they are working.

Last February was a highlight in the council's osteoporosis education campaign. On February 6, we produced a live teleconference transmitted via satellite to 50 sites around the country where health professionals participated in the 2½-hour teleconference. There was a very distinguished speakers panel of four researcher

physicians and the panel's moderator, Dr. Philip White, of the American Medical Association. This teleconference was attended by 5,500 health professionals.

As a followup to this activity, we are making video tapes of the teleconference available to hospital libraries and to medical school facilities so the information can be provided at a later date to physicians and to dieticians who did not have an opportunity to attend the teleconference.

About 67 percent of the participants in the teleconference were registered dieticians. The remainder of the audience was composed of physicians and other health education professionals.

Just a last word about some of our research efforts. We have 23 research projects in the area of calcium and bone health, and the results from these research projects will be made available, not only through publications and health professional journals, but also through a program we have called the visiting professor in nutrition. Under this program speakers are supplied at medical and dental institutions' requests to talk on the topics of calcium and bone health and to relate the latest research in these areas to the faculties of these institutions.

These are some of the highlights of our public education program and our education for health professionals over the last 2 years. It is our intention to continue this effort, this campaign, because we know that the extent of this public health problem is such that it is going to take a continuing effort in order, first of all, to make people aware of it, and then, second, to consider changing their lifestyles to prevent it. Initially we are aiming the campaign at the 20- to 35-year-old group. We know it is going to take a continued effort and we plan to continue this education campaign in the coming years.

[The prepared statement and additional material of Dr. Kinney follows:]

Hearing on

Osteoporosis

United States Senate

Committee on Labor and Human Resources

Subcommittee on Aging

Statement by
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National Dairy Council
6300 North River Road
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June 20, 1985

Osteoporosis Hearing

Subcommittee on Aging

Senate Committee on Labor and Human Resources

June 20, 1985

I am Gloria Kinney, Vice-President for Nutrition Education, National Dairy Council. I want to thank you for inviting National Dairy Council (NDC) to provide the Subcommittee with information on our activities in nutrition education and research relating to calcium, bone health, and osteoporosis.

National Dairy Council was established in 1915 as an educational-scientific organization on the advice of Dr. E.V. McCullom of the University of Wisconsin. After Dr. McCullom discovered Vitamin A in milkfat, he recommended that the dairy industry, as a public service, educate the American public about the health "protective values" of the nutrients in milk and dairy foods. National Dairy Council was established by the dairy industry in response to that historic advice and has been providing nutrition education services to the American public since that time. Nutrition education has been the basic mission of the National Dairy Council for the last 70 years.

Early in the 1920's it was recognized that in America, education is a grass-roots, community-based function. And so, over the years, the dairy industry has organized and supported local Dairy Council units affiliated with National Dairy Council to carry out nutrition education programming at the local, state and regional levels. It was also recognized in those early years that no single food or food group contains all of the nutrients essential for health. Thus early on, the nutrition education programs of Dairy Council were based on teaching the American public the importance of eating in moderation a wide variety of foods from the major food groups as the foundation of a healthful diet.

Today there are 33 affiliated Dairy Council Units with offices in 126 locations across the nation and approximately 250 staff members with professional backgrounds in home economics or dietetics to carry this message to the American public. As special needs or circumstances arise, such as the current public health concern related to osteoporosis, Dairy Council's educational network can be mobilized to deliver important messages related to nutrition, health promotion and disease prevention to the general public.

Over the last two years the primary focus of Dairy Council's educational programming has been on the calcium needs and deficiencies in the American diet and on the prevelance and prevention of the bone disease, osteoporosis. We have accelerated Dairy Council's development and delivery of educational materials and programs on osteoporosis, both to health care professionals and to consumers. We have stepped up our research on calcium's role in the development and maintenance of bone health and on calcium requirements at various ages and stages in life.

Since November, 1984,National Dairy Council has been greatly assisted in these nutrition education and research endeavors by additional funding provided by the National Dairy Promotion and Research Board, Arlington, VA. The Board was established by Act of Congress to develop a coordinated program of promotion designed to strengthen the dairy industry's position in the marketplace and to maintain and expand domestic and foreign markets and uses for fluid milk and dairy products.

I Health Professionals

Over the last two years, 1984-85, the following education materials and program services on calcium and bone health have been made available by Dairy Council to health professionals:

A. Calcium: A Summary of Current Research for the Health Professional is a referenced handbook that reviews the recent research on calcium

requirements throughout the life cycle and discusses the diseases associated with chronic calcium deficiency. Included in the handbook are duplicating masters for client education materials on calcium, fat, cholesterol and sodium. Also included are sample copies of consumer and client information brochures on calcium-related topics available from National Dairy Council. A total of 67,000 copies of this reference manual on calcium has been distributed to health professionals to date. A sample copy of this publication is provided as Attachment #1.

B. Dairy Council Digest

The January-February, 1984 issue of the Dairy Council Digest, "The Role of Calcium in Health," provides a comprehensive review of the role of calcium in the body, recent calcium consumption statistics, a discussion of the health implications of an inadequate calcium intake, calcium requirements and sources of calcium in the food supply. Approximately 100,000 copies of this issue of the Dairy Council Digest were disseminated to health professionals and nutrition scientists. A sample copy is provided as Attachment #2.

C. Nutrition News

During 1984, three issues of this quarterly publication were devoted to the topics of calcium and bone health. Nutrition News reaches approximately 80,000 health educators with each issue.

Feb. 1984 - "Calcium Absorption and Requirements during the Life Span: by Lindsay H. Allen, Ph.D., R.D. reviews calcium metabolism and requirements and the effect of various dietary factors on calcium absorption. It discusses the osteoporosis problem and its relationship to dietary calcium intake at various life stages. A sample copy is provided as Attachment #3.

April, 1984 - "The Role of Calcium in Bone Health" by Robert R. Recker, M.D., reviews growth and development of the skeleton and discusses age-related bone loss in women. Diet as well as physical activity and other lifestyle considerations are reviewed and recommendations are made for increased calcium intake at certain stages in life. A sample copy is provided as Attachment #4.

Dec. 1984 - "Nutrition and Aging: The Challenges" by Hamish N. Munro, D.Sc., M.B., reviews the conditions of diet and lifestyle which best preserve bodily functions in the adult. Nutrient needs of the elderly as well as malnutrition among aging populations are discussed. In this same issue, "Nutrition and Bone Health: An Exercise in Continuing Medical Education" by Wendy Lippman of the University of Washington, Seattle, presents information on the work of the research team led by Charles H. Chesnut III, M.D., to develop new treatments and preventive measures for osteoporosis. A sample copy is provided as Attachment #5.

D. Calcium: A Research Update, a video teleconference

On February 6, 1985 a live teleconference, Calcium: A Research Update was conducted for health professionals to provide them with information on recent research findings on calcium's relationship to bone disease and hypertension. The teleconference was attended by 5500 health professionals, predominately registered dietitians, at 50 downsites across the country. Audiences had an opportunity to participate in question/answer and discussion sessions with the distinguished calcium researchers on the teleconference faculty. Reference materials and client education materials on calcium and bone health were provided to teleconference participants.

The first segment of the teleconference featured Charles H. Chesnut III, M.D., University of Washington School of Medicine, Seattle, Washington and Robert R. Recker, M.D. of Creighton University, Omaha, Nebraska. Philip L. White, Sc.D. of the American Medical Association moderated the discussion and the question and answer session which followed the presentations. A copy of the teleconference videotape as well as a copy of the information packets on calcium distributed to the attending health professionals have been provided to the Subcommittee staff for reference. The teleconference concluded with a discussion on hypertension.

As a follow-up activity to extend its impact, 500 videotapes of the teleconference will be placed in medical school libraries, hospitals and with health professional associations.

E. Diagnosis: Calcium Deficiency--An exhibit for health professionals

An exhibit highlighting the health risks of bone disease associated with chronic calcium deficiency in the diet has been on display at health professional meetings since mid-1984 and will continue to be on display throughout 1985. A total of 12 national meetings of health and education professionals, with a estimated attendance of 100,000, will be reached by the exhibit. The exhibit features calcium-related education materials developed by National Dairy Council. Advertisements placed in professional journals also have alerted health professionals to Dairy Council's calcium-related materials, informational services and the calcium exhibit.

F. Visiting Professorship in Nutrition Program

The purpose of the Visiting Professorship in Nutrition program is to enhance the present level of nutrition knowledge of physicians, dentists, medical and dental students and other health care professionals. The

program is designed to create a greater awareness of the importance of nutrition to clinical medicine, dental health and other closely related specialties. Several professors (13 in the medical and 3 in the dental program) with expertise in calcium, bone metabolism and osteoporosis are included in the program. Attachment #6 contains a listing of visiting professors currently available to speak on topics related to calcium, bone health and osteoporosis.

G. Calcium-related Conferences and Symposia

The purpose of these conferences is to provide a forum for discussing the latest scientific findings and to update the health professional community on the science and application of these findings. Attachment #7 provides a listing of recent calcium-related nutrition conferences that NDC has sponsored or cosponsored with other scientific and professional organizations.

H. Additional Materials

Over the years National Dairy Council has developed many basic nutrition education resource and reference materials for health professionals who work with consumers to help them select a nutritionally-adequate diet, including calcium from Milk Group foods. Especially useful are:

Food Models

Comparison Cards

The Guide to Good Eating

Contemporary Topics in Nutrition

Nutrition Source Book

Weight Management: A Summary of Current Theory and Practice

Lifesteps: Weight Management Program

Brief descriptions of these nutrition education materials and resources are contained in National Dairy Council's Nutrition Education Materials Catalog for 1985-86. A copy of this catalog is provided as Attachment #8.

II Consumer Education Materials and Services

Over the last two years, 1984-85, the following consumer education materials and program services have been published by National Dairy Council for consumers:

A. Calcium: You Never Outgrow Your Need For It reviews the body's need for calcium, particularly for proper skeletal growth, development and maintenance at different ages and stages of the life cycle. (Attachment #9)

B. Are You At Risk For Bone Disease? outlines the risk factors associated with osteoporosis and the positive steps people can take to maintain good bone health. (Attachment #10)

C. The All-American Guide to Calcium-Rich Foods explains the importance of calcium to good health and helps consumers identify the major sources of calcium in their diet. (Attachment #11)

D. Sticks and Stones Can Break Your Bones...And So Will Too Little Calcium debunks six common myths held by many consumers about calcium and dairy products. (Attachment #12)

E. Like Mother, Like Daughter: A Woman's Guide to Bone Health explains what osteoporosis is, how it cripples the body and what women can do to prevent this insidious disease. (Attachment #13)

F. For Mothers-To-Be: How to Build a Better Baby outlines the dietary needs of pregnant women, putting special emphasis on the need for calcium during pregnancy and through the adult years. (Attachment #14)

G. For Young Mothers-To-Be: How to Take Care of Yourself and Your Baby is designed to help young mothers (women under 19) meet their own nutrient

needs during pregnancy as well as the nutrient needs of their unborn children. (Attachment #15)

H. Osteoporosis, a consumer education brochure developed by the Washington State Dairy Council and produced by NDC, identifies the scope and significance of the problem, its causes and examines dietary sources of bone-building nutrients. The prevention of osteoporosis is stressed as a lifelong endeavor. (Attachment #16)

I. Osteoporosis: Are You At Risk For Bone Disease?, a color, sound, 16mm film, is designed for adults (primarily women), teenagers, and health professionals. This 15-minute film increases awareness of the bone disease, osteoporosis -- what it is, who is at risk for it, and what can be done to prevent it. These questions are answered in the film by medical experts and dramatized by actors. The importance of lifelong dietary calcium intake and physical activity are emphasized. A Leader's Guide is provided to those using the film which contains information on osteoporosis in the form of often-asked questions and their answers. A 8-minute excerpt from the film on videotape has been provided to the staff of the Subcommittee. A sample copy of the Leader's Guide which accompanies the film is provided as Attachment #17.

J. Osteoporosis and You is a consumer education slide-tape presentation. Designed for adults (primarily women), this 20-minute slide-tape presentation discusses osteoporosis, and the preventive measures that can be taken in diet and physical activity to reduce the risk of developing the disease. Developed by the St. Louis District Dairy Council and produced by NDC, Osteoporosis and You is presented to consumers by volunteer speakers. A packet of training and promotion materials developed to support the presentation has greatly increased and enhanced its dissemination to consumers. A copy of the tape-slide presentation,

has been provided to the staff of the Subcommittee for reference. A copy of the promotion brochure for the presentation is provided as Attachment #18.

K. Consumer Exhibits: Calcium and Bone Disease

A set of 126 exhibits on Calcium and Bone Disease developed by NDC are currently on nationwide display.

These large free-standing exhibits feature information on the risk factors for osteoporosis, calcium needs throughout the lifecycle, calcium sources in the American diet, and the special calcium needs of women at various times in their lives. The exhibits are on display at supermarkets, health fairs, shopping malls, hospital and office building lobbies, airports, etc. The exhibit panels are coordinated with the consumer education brochures described above and feature these brochures as take-away handouts. A photograph of the exhibits is provided as Attachment #19. Copies of the consumer take-away literature featured in the exhibit are provided as Attachments #9 through #16.

L. Media Tours

The purpose of the Media Tours is to take highly qualified speakers directly to the electronic and print media in different cities nationwide to talk about nutrition topics of interest to consumers. A listing of the speakers on calcium and bone research sponsored on NDC Media Tours is provided in Attachment #20.

M. Additional Materials

Over the years National Dairy Council has developed many nutrition education materials for consumers. These materials are designed to help consumers of all ages select a nutritionally-adequate diet,

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including calcium from Milk Group foods. Especially useful in addition to the specific calcium-related materials described earlier are:

Food Models

Comparison Cards

Consumer Information Series of Brochures:

- For Mature Eaters Only
- Supermarket Survival
- What to Know About a Weight-Control Diet before You Eat One
- The Limitations of Imitations
- Fast Foods
- Nutrition Myth-Information

Consumer Product Information Sheets:

- Milk
- Ice Cream
- Cheese
- Yogurt
- Cottage Cheese
- Butter-Cream
- Sour Cream

Guide to Wise Food Choices

Your Calorie Catalog

From Birth to Birthday

Partners in Growth

Spice of Life (a film for older adults)

Wholly Cow (a film for children and adults on Milk Production)

Food...Your Choice Learning System for consumers aged 3 to 18.

The above listed materials are briefly described in the National Dairy Materials Catalog for 1985-86 supplied as Attachment #8.

III Nutrition Research Grant-in-Aid Program

A major component of National Dairy Council's Nutrition Research Program is the grants-in-aid provided to investigators at medical schools, colleges and universities and other scientific institutions throughout the United States.

In January, 1985, the National Dairy Promotion and Research Board funded 19 research projects in the areas of calcium and bone health. These nutrition research grants are administered by National Dairy Council for the National Dairy Board. In addition, NDC has funded four research grants in the calcium and bone, health areas. A listing of these 23 projects and the investigators and institutions to which these grants-in-aid were made is provided as Attachment #21.

This research effort is coordinated with NDC's nutrition education materials and programs on calcium, bone health and osteoporosis, providing a scientific base for their development. The findings from these 23 research projects will be disseminated to the health professional community and to consumers through the media, the Visiting Professor in Nutrition program for medical and dental schools, and through Dairy Council's nutrition education programming. In addition, the research findings will be published in health professional journals to alert the health professional community to their implications for the treatment and prevention of osteoporosis.

IV The National Dairy Promotion and Research Board

The National Dairy Promotion and Research Board was established by an Act of Congress to develop a coordinated program of promotion designed to strengthen the dairy industry's position in the marketplace and to maintain and expand domestic and foreign markets and uses for fluid milk and dairy products. In addition to product advertising and product research, nutrition education and nutrition research are supported as an integral part of the total promotion program.

In November, 1984, the National Dairy Research and Promotion Board provided National Dairy Council with funding to conduct four Information/Awareness projects on calcium and bone health. In March, 1985 this calcium campaign was augmented and extended with additional funding from the Board. To date, a total of $899,100 has been made available to National Dairy Council and its affiliated Dairy Council units to conduct the following nutrition education activities on calcium and bone health:

For health professionals:

1985 Teleconference--Calcium: A Research Update

Exhibit -- Diagnosis: Calcium Deficiency

For consumers:

Exhibits on Calcium and Osteoporosis

Workshop -- Osteoporosis and You

V. Closing Comments

Osteoporosis is a major public health problem facing an ever-increasing number of Americans. It is a powerful and debilitating disease. National Dairy Council has undertaken a major effort to educate the general public as well as the health professionals who provide advice and counsel on the risk factors

associated with osteoporosis, and on the lifestyle changes which can be taken to help prevent or delay its development. Attachment #22 provides a listing of recent National Dairy Council testimony and comments regarding the need to educate the public about the importance of adequate calcium intakes throughout life as a preventive measure against osteoporosis.

We believe it is of great national importance to maintain these educational efforts and to continue building the scientific data base that provides the foundation for these efforts.

EDITOR'S NOTE: Due to printing limitations and in the interest of economy, the attachments listed below were retained in the files of the committee where they may be researched upon request.

LISTING OF ATTACHMENTS

Attachment # 1 Calcium: A Summary of Current Research for the Health Professional

2 Dairy Council Digest, Jan.-Feb. 1984, The Role of Calcium in Health

3 Nutrition News, Feb. 1984, "Calcium Absorption and Requirements during the Life Span"

4 Nutrition News, April 1984, "The Role of Calcium in Bone Health"

5 Nutrition News, Dec. 1984, "Nutrition and Aging: The Challenges"

6 Visiting Professorship in Nutrition for 1986, Calcium, Bone Health and Osteoporosis

7 Recent Calcium-Related Nutrition Conferences Sponsored or Cosponsored by National Dairy Council

8 National Dairy Council, Nutrition Education Materials Catalog, 1985-86

9 Calcium: You Never Outgrow Your Need for It

#10 Are You At Risk For Bone Disease?

#11 The All-American Guide to Calcium-Rich Foods

#12 Sticks and Stones Can Break Your Bones...And So Will Too Little Calcium

#13 Like Mother, Like Daughter A Woman's Guide to Bone Health

#14 For Mothers-To-Be: How to Build a Better Baby

#15 For Young Mothers-To-Be: How to Take Care of Yourself and Your Baby

#16 Osteoporosis

#17 Osteoporosis: Are You At Risk for Bone Disease? Leader's Guide.

#18 Osteoporosis and You, Promotion Brochure

#19 Photograph of National Dairy Council Consumer Exhibit on calcium and bone disease.

#20 Media Tour speakers on Calcium and bone research

#21 1985 Nutrition Research Projects related to Bone Health and the Availability of Calcium for Bone Health.

#22 Recent National Dairy Council testimony and comments on calcium and bone health.

Senator HAWKINS. Thank you, Doctor.

Do you know how much the Dairy Council spends on advertising?

Dr. KINNEY. The Dairy Council spends very little on advertising. A related dairy organization, the American Dairy Association, is really the industry's advertising and promotion agency. I do not know the extent of the funding they are putting into advertising at the present time, or the extent of the advertising funding that has been provided by the new National Dairy Promotion & Research Board.

Senator HAWKINS. There was a checkoff on that, price supports for dairy products.

Dr. KINNEY. Yes, but as for National Dairy Council, our only advertising on TV is the public service announcements that we develop and make available.

Senator HAWKINS. These tapes you distribute to professionals, are they too technical to distribute to the centers that Senator Matsunaga is talking about?

Dr. KINNEY. No. Apparently the staff of those centers would profit from the tape of the teleconference. I expect that the people who are in the nursing centers who have the disease would probably enjoy one of our other publications for consumers to a greater extent—either the slide-tape presentation or the film that I mentioned. The film is available on tape as well as 16-millimeter format. They would probably be of more interest to the people in the nursing homes.

Senator HAWKINS. You do have a videotape? Did I not see one?

Dr. KINNEY. Yes. And I have made available a short clip from the osteoporosis film to the staff. I also have a tape of the teleconference, the more technical presentation from the physicians, that is also available for health professionals.

Senator HAWKINS. One last question for Dr. Peck. Cuban-Americans in my State have cafe au leche for breakfast. It is a cup of milk with maybe a tablespoon of coffee each morning and that is it. Americans have scrambled eggs and they have coffee later. But the first thing at the table is cafe au leche. I like milk and that is the only way I can drink the coffee, with a tablespoon in a cup of milk, and I notice at a breakfast of 20 men, Cuban-Americans, that is brought to them first, at least two cups before they bring the breakfast at the meeting, I have been told for the last 10 years. I just mention it because you are doing research and I would like to see if that has had any impact on the density of their bones. That is a segment of the American population that probably has been here 25 years and their children also. So you would have the two generations that brought this custom with them to my State as well as other areas where they live. We have a large Cuban population, and I would suggest to you that perhaps some cross-cultural studies might include Cuban Americans. As we talk about the Federal Dairy Program, as I wrestle with the price supports for milk and as the taxpayers pay the storage costs for that milk all over this country, it seems to me that we have a problem, we know it is a problem, epidemic levels. We have some of the solution in storage and the Government is helping pay and we can prevent it. We have learned over and over again today it can even be a do-it-your-

self, early-in-life approach. So I think there is some merit to cross-cultural studies that you might want to discuss with my staff.

Dr. PECK. Thank you. Good suggestion.

Senator HAWKINS. Senator Matsunaga.

Senator MATSUNAGA. Thank you, Madam Chairman.

I want to congratulate you, too, Dr. Kinney, and the National Dairy Council. I had no idea you were doing the things you described today and if it is advertising in any way I think it is the most productive and most effective way of advertising. Do you have a chapter of the council in Hawaii?

Dr. KINNEY. Unfortunately, we do not. We do not have one in Alaska or Nevada. Those are the three States right now that do not have a Dairy Council unit. However, because they are on the mainland, both Alaska and Nevada do receive some services from nearby Dairy Councils, We would like very much to have a Dairy Council in Hawaii.

Senator MATSUNAGA. I wish you would go there. What do you do about the Oriental stomach that cannot digest milk? Do you have any substitute or combination of milk and something? Both my parents could not take milk and as a child I drank a lot of milk because one of my older brothers worked at a dairy and he brought home free milk. I learned to drink milk. But about 15 years ago I suddenly discovered I could not take milk anymore. It serves as a laxative to me, and this is true with most of my Oriental friends who are now senior citizens. They just cannot take milk. Why is that? Is there a substitute for milk?

Dr. PECK. The condition you are talking about in all likelihood is known as lactose intolerance. Lactose is the sugar in milk which some people cannot digest, and it does act as a very unpleasant laxative, as you know. And the prevalence of this problem is very, very high. It is a deterrent to milk usage and older people are afflicted with it more commonly than young people. It's incidence increases with age. So consequently milk and milk products that contain lactose cannot be consumed and one has to turn to other sources of calcium to enrich your diet and protect your bones.

Senator MATSUNAGA. Like what?

Dr. PECK. In terms of dietary sources, yogurt, for example, is a milk product in which the lactose has been digested during its preparation so, consequently, it is relatively safe for these people. Other forms of dietary calcium include leafy vegetables, nuts, small fish such as anchovies and so forth. But most people are not going to eat enough of those kinds of foods to satisfy the need for a thousand milligrams or 1,500 milligrams of calcium daily. So, consequently, most physicians, experts in osteoporosis will prescribe calcium supplements, in tablet or liquid form for those individuals.

Senator MATSUNAGA. I wish as a researcher—you are a researcher, are you not?

Dr. PECK. Yes.

Senator MATSUNAGA. You might be able to do something to get the lactose out of milk so we can use all the surplus milk that the Government pays for. Thank you.

Dr. KINNEY. I would just like to add there has been some research that has been done in this area. Acidophilus milk is a result of some of that research; it is an attempt to do just exactly what

you asked. Also, if you consume milk in small amounts or with other foods, rather than taking a large amount at one time, that also seems to help in some cases.

Senator HAWKINS. Do very many people know about acidophilus milk? I use it, but people always say what is that when they see it in the refrigerator. Has that had an education program out there?

Dr. KINNEY. There has not been an extensive education program on that yet. It is fairly widely distributed but in some parts of the country it still is not totally available. However, it does seem to be one of the newer products that may in the future offer a considerable help to people who have difficulty digesting the lactose in milk.

Senator HAWKINS. We want to thank all of you for participating here today. We have learned a lot. I think we have learned a lot more needs to be learned. Information needs to be distributed. At least we are increasing public awareness. We can make recommendations for a better diet, more exercise and prevention is clearly the key, I feel, when it comes to Government expenditures on the figures that we are talking about as we see the graying of America.

Thank you all for your contributions to this.

Senator MATSUNAGA. Can I ask unanimous consent from Senator Pell to have his opening statement included in the record.

Senator HAWKINS. Surely. We will keep the record open the rest of the day for statements of members of the committee if there are any and answers to any questions which will be submitted to you who are members of the panel. We appreciate your participation. Thank you.

[Additional material submitted for the record follows:]

JUNE 20, 1985

TESTIMONY OF THE NATIONAL WOMEN'S HEALTH NETWORK
ON OSTEOPOROSIS
BEFORE THE SUBCOMMITTEE ON AGING OF THE
COMMITTEE ON LABOR AND HUMAN RESOURCES

The National Women's Health Network, a national public interest organization devoted exclusively to women's health, represents 500,000 women across the country, a combination of individual and organizational members. The Network seeks to "give a woman's voice" to the health care system in the United States, and it represents the Women's Health Movement to the federal regulatory agencies and health policymakers.

The Network recognizes the value of analyzing and validating women's actual experiences with medical treatments and devices as well as medical and laboratory research. As a result, the Network has been instrumental in identifying to the federal regulatory agencies potentially harmful and life-threatening aspects of drug usage and medical devices which might otherwise have gone unaddressed.

We commend the Subcommittee on Aging for their interest in osteoporosis, a condition of decreased bone mass linked to fractures and a disruption in the normal structural integrity of the skeleton. Osteoporosis affects more than four million women in the United States. After the late seventies, osteoporosis in men occurs with the same degree of frequency as in women.

Recently, there has been an upsurge in public education about osteoporosis, emphasizing preventive measures including nutrition, exercise and estrogen replacement therapy. Such campaigns have been directed to women aged thirty-five and older; thirty-five is

the age which has been identified as the beginning of loss of bone density.

Medical journals are no longer the sole purveyors of information on osteoporosis; women's magazines now bring this information to millions of readers across the U.S. through advertising, and health columns and articles. Osteoporosis is gaining recognition and attention from those who may suffer its effects.

(As an organization which has advocated for consumer access to health and drug information for the past ten years, we consider this significant progress.)

BUT NOT ENOUGH IS KNOWN ABOUT OSTEOPOROSIS AND ITS TREATMENT. And until more research is done, there is a danger that existing treatment for osteoporosis may be mass marketed and that women will once again be guinea pigs for medical treatments which could prove to be fatal.

Thousands of women have suffered ill effects and death as a result of being prescribed hormones which still are not tested, or are not prescribed with consideration of the individual's medical history, including previous hormonal treatment or ingestion, and her nutrition, exercise and lifestyle (eg. smoking, stress, children, etc.).

MORE RESEARCH NEEDS TO BE DONE ON OSTEOPOROSIS.

The vast majority of current research projects on osteoporosis are funded by pharmaceutical companies with a vested interest in osteoporosis. A portion of the research is supported by food trade associations who also have a vested interest. There are very few "unaffiliated" research programs on osteoporosis. Independent research must be expanded.

THE DIRECTION OF RESEARCH ON OSTEOPOROSIS SHOULD INCLUDE CONSIDERATION OF LIFELONG PATTERNS OF NUTRITION AND EXERCISE RATHER THAN VIEWING OSTEOPOROSIS SOLELY AS A RESULT OF HORMONAL DEFICIENCY.

Thanks in large part to sex-role stereotypes, the generation of women with osteoporosis currently being studied was groomed to be sedentary and slim. This effectively ruled out regular exercise and supported poor dietary habits, including crash dieting (which often eliminates important sources of calcium). There has been some reversal of osteoporosis with changes in exercise and nutrition, and this needs further exploration.

Additionally, public education on osteoporosis should be incorporated into school health and family life curricula with an emphasis on the preventive aspects of nutrition and exercise.

UNTIL FURTHER RESEARCH IS DONE, HORMONAL TREATMENT FOR OSTEOPOROSIS SHOULD BE GIVEN ONLY IN SPECIAL CIRCUMSTANCES, AND SHOULD BE CAREFULLY MONITORED FOR SHORT AND LONG-TERM SIDE EFFECTS. THE SPECIAL CIRCUMSTANCES IN WHICH HORMONAL TREATMENT IS PRESCRIBED SHOULD BE INCLUDED IN THE RESEARCH ON OSTEOPOROSIS BY AN INDEPENDENT AGENCY.

Hormonal treatment is not indicated for all women who have osteoporosis, nor for all women who may have it in the future. Information on estrogen replacement therapy is neither complete nor consistent. There is conflicting information on dosages, and on the link of such treatment to gall bladder disease, endometrial cancer, hypertension, fibrocystic disease and exacerbation of uterine fibroids. Management of these latter problems is sometimes suggested by the introduction of progesterone (another hormone), which may be responsible for an increased risk of significant vascular and heart problems.

In our modern age, it is both easy and inviting to rely on medical treatment and drugs as the panacea they are often promised to be. The public must be informed of the possible dangerous side effects of hormonal treatment and of alternative measures which may be taken in the treatment of osteoporosis.

Please contact the National Women's Health Network for more information on women's reactions to hormone treatment, or additional information on nutrition and exercise in the treatment of osteoporosis.

National Women's Health Network
224 7th Street, SE
Washington, DC 20003

STATEMENT

Submitted to the
Subcommittee on Aging
of the
Senate Committee on Labor and Human Resources
by
Joseph J. Westwater
Chief Executive Officer
National Dairy Promotion and Research Board

The National Dairy Promotion and Research Board appreciates this opportunity to present information on its osteoporosis research and education programs.

The Board was created by an Act of Congress to implement a national program for dairy product promotion, research and nutrition education as an effort to reduce milk supplies and increase the consumption of dairy products. This self-help program is funded entirely by the nation's dairy farmers, who pay a mandatory 15-cent assessment on every 100 pounds of milk produced in the contiguous 48 states. As required by law, the Secretary of Agriculture is conducting a referendum during August, 1985, to determine whether a majority of the dairy producers favor the continuation of the program. If continuation does not receive a majority vote, the program will be terminated, as the law requires.

Osteoporosis is a painful and crippling disease that affects 15-20 million Americans, primarily women over age 50. Inadequate calcium intake is a leading factor in the development of osteoporosis, which is becoming a greater problem as the U.S. population ages.

Milk and milk products (cheese, yogurt, ice cream) contain a concentrated supply of available calcium. Three quarters of the calcium in the American diet comes from milk products. The remaining quarter is supplied by foods from the Meat, Fruit-Vegetable and Grain Groups.

Studies have shown that the average American diet is lacking in this essential nutrient which combats osteoporosis. According to the National Institutes of Health (NIH), "the usual daily intake of elemental calcium in the U.S. is 450 mg. to 550 mg." Although the current recommended daily allowance (R.D.A.) for calcium is 800 mg.,[1/] NIH and others in the medical community recommend a daily intake of 1,000-1,500 mg.[2/]

Insufficient intake forces the body to use calcium stored in the bones, leading to a weakened, brittle condition that becomes especially acute in later years. Approximately 1.3 million bone fractures are attributed to osteoporosis annually, including 150,000 hip fractures. A quarter of those who suffer hip fractures die within a year of the accident. Osteoporosis may also lead to spinal curvature and a loss of height ("dowager's hump").

Health care costs associated with osteoporosis approach $3.8 billion each year. Most of these costs are paid by the U.S. taxpayer through Medicare and Medicaid programs because the disease affects older individuals the most severely. Osteoporosis is estimated to affect 61 percent of the women aged 55-64 and 76 percent of women aged 65-74.

The National Dairy Board funds the majority of osteoporosis research and a large portion of the osteoporosis education projects carried out by the dairy industry. More than $3 million of the promotion and research funds provided by the nation's dairy farmers have been allotted to this effort. In addition, a significant portion of the Board's more than $60 million advertising budget is devoted to informing women about their need for calcium.

Specifically, the Board is funding 25 research projects on the role of calcium in the life cycle at a total of $1.271 million. A list of these studies and the funding for each is attached to this statement. In addition, $2.149 million is being spent on the following four calcium education and information programs aimed at health professionals and consumers.

A Calcium Information/Awareness Plan

The plan will reach a wide audience through four components:

- A satellite teleconference targeted to the health community was held February 6, 1985. More than 5,000 health professionals gathered at 50 sites in the U.S. for a 2-1/2 hour update on calcium in relation to bone health and hypertension.

- A Calcium Exhibit with related printed materials was displayed at the annual meetings of the American College of General Practice (March 1985) and the American Occupational Medical Association (April 1985).

Dairy Board funds have been provided to show the exhibit at eight additional health professional meetings.

- Dairy Council units are exhibiting 126 Board-sponsored consumer displays on calcium in a variety of high traffic locations estimated to attract a million viewers.

- A Board-funded slide/tape show on osteoporosis with supplemental print material is used as the focal point of Dairy Council consumer workshops.

Nutrition Education for the Health Professional Community

Calcium advertisements have been scheduled to appear in 13 leading medical journals and magazines from January through November, 1985. The ads, containing a coupon for calcium materials and a toll-free quick response number, will reach an unduplicated readership of 171,000.

Physician information, a dairy diet pad and patient brochures were mailed to 20,000 OB/GYN specialists.

Nutrition Education for Consumers

This comprehensive information program is aimed at food, nutrition and health communicators. The major elements include production and distribution of news releases, photo releases, camera-ready news copy, a quarterly newsletter and a 16-site teleconference on calcium.

Supermarket Calcium Consumer Education

An eight-month program has been designed to bring the calcium message to four target groups -- children, teens, young adult women and mature women -- through supermarkets.

Stores are provided with leaflets, recipe cards and tear-off pads, audio tapes, videotapes and other promotional materials. To increase awareness of the effort, information on the program is provided to 62 supermarket trade magazines.

The first kit, "Calcium and the Active Young Woman," was used by 150 chain and independent operations representing 19,643 stores.

The National Dairy Board is reaching an even wider audience with the inclusion of osteoporosis information and the need for calcium in its national advertising campaign. The dangers of osteoporosis are mentioned in the copy of a variety of print advertisements run in consumer magazines nationwide.

The majority of print advertising run since January, 1985 either mentioned osteoporosis or the important role of dairy calcium in promoting bone health. Since the first of the year, nine different advertisements were placed in 93 positions in 28 national magazines. A list of the placements, totalling $2.3 million, is attached to this statement along with a sample of the advertisements.

The National Dairy Promotion and Research Board has taken an active role in the fight against osteoporosis. We appreciate the efforts made by this committee and other Members of Congress to raise public awareness and encourage further research on this condition.

Footnotes

1/ 800 mg/day for ages 1-10.
1,200 mg/day for ages 11-18.
800 mg/day for ages 19+.
An additional 400 mg/day is recommended during pregnancy and lactation.

2/ 1,000 mg/day for premenopausal and estrogen-treated women.
1,500 mg/day for postmenopausal women not treated with estrogen.

ATTACHMENT A

Calcium Throughout the Lifecycle

The Projects	Amount Funded
John J. B. Anderson, Ph.D. & Roy V. Talmage, Ph.D. University of North Carolina "Dietary Calcium Intakes and Bone Mineral Density in College-Age Women"	$27,500
Daniel T. Baran, M.D. University of Massachusetts "Efficacy of Oral Calcium Supplementation (Dairy Products) in the Prevention of Age-Related Bone Loss in Premenopausal Women"	$37,500
David J. Baylink, M.D. Loma Linda University "Maternal Calcium Requirements During Pregnancy and Lactation"	$22,000
Anne Manon Brenner, M.D. National Jewish Hopsital & Research Center/National Asthma Center "The Role of Dietary Calcium in Attenuating Osteoporosis in Steroid-Treated Asthmatic Children"	$27,500
V. Matkovic, M.D. & Charles H. Chesnut III, M.D. University of Washington "Influence of Calcium on Peak Bone Mass"	$59,000
William A. Stini, Ph.D. University of Arizona "Consumption of Dairy Products, Exercise and the Retention of Bone Mineral in an Affluent Retirement Community"	$20,000
Gordon Wardlaw, Ph.D., M.P.H., R.D. University of Utah "The Effect of Simultaneous Hypocalciphagia and Multiparity on Peak Adult Bone Mass in Women"	$11,000
Christopher E. Cann, Ph.D. University of California - San Francisco "Dietary Calcium, Reproductive Endocrine Status, and the Athletic Woman"	$45,600
William J. Evans, Ph.D. & Bess Dawson-Hughes, M.D. USDA Human Nutrition Research Center on Aging at Tufts "The Role of Calcium and Physical Activity in the Prevention of Age-Related Loss in Bone Density"	$55,000
Barbara L. Drinkwater, Ph.D. & Charles H. Chesnut III, M.D. Pacific Medical Center, Seattle, Washington "Role of Calcium and Estrogen in Reversing Bone Loss in Exercise-Associated Amenorrheic Athletes"	$182,500

The Projects	Amount Funded
Wiltz W. Wagner, Jr., Ph.D. University of Colorado Health Science Center "Skeletal Integrity and Diet in Female Runners"	$21,500
H. James Armbrecht, Ph.D. VA Medical Center, St. Louis, Missouri "Age and the Enhancement of Mineral Absorption by Milk Constituents"	$32,000
Mona Schiess Calvo, Ph.D. & Hunter Heath III, M.D. Mayo Clinic & Foundation "The Effects of High Phosphorus Intake on Mineral Regulating Hormone Response in Humans"	$20,000
Scott C. Miller, Ph.D. University of Utah "The Role of Lactose in Promoting Skeletal Development, Growth and Remodeling"	$21,000
Janet L. Greger, Ph.D. University of Wisconsin "Effect of Milk Versus Calcium and Phosphorus Supplements on Calcium, Phosphorus and Trace Element Utilization"	$21,500
Robert P. Heany, M.D. Creighton University "Anion Effects of Calcium Supplements on Bone and Calcium Metabolism"	$58,000
Michael Liebman, Ph.D. University of North Carolina "A Comparative Study of Calcium Bioavailability from Cheese, Spinach and Soybean Curd (Tofu) as Assessed by Calcium Balance in Adult Women"	$30,000
Lawrence G. Raisz, M.D. University of Connecticut Health Center "Effects of Calcium on Bone Mass in Premenopausal Women"	$56,000
Herta Spencer, M.D. VA Medical Center, Hines, Illinois "Calcium Bioavailability from Various Foods (Including Dairy Foods)	$27,500
Elizabeth J. Dial, Ph.D. & Lenard M. Lichtenberger, Ph.D. University of Texas "The Role of Milk Lipids in Gastric Cytoprotection"	$22,500
Moshe Levi, M.D. University of Texas Health Science Center "Role of Dietary Calcium in Acute Renal Failure in the Young and Aged: Cellular and Hemodynamic Events"	$29,500

The Projects	Amount Funded
George M. Patton, Ph.D. & K. C. Hayes, D.V.M., Ph.D. VA Medical Center, Boston, Massachusetts "Role of Dietary Induced Changes in Individual Molecular Species of Phosphatidyl Choline on Arterial Cholesterol Deposition and the Development of Atherosclerosis in Primates"	$47,000
Dennis A. Savaiano, Ph.D. & Michael D. Levitt, M.D. University of Minnesota "Digestion of Fermented Dairy Products by Lactose Intolerant Individuals"	$20,000
Charles F. Schachtele, Ph.D. University of Minnesota "Evaluation of the Anticariogenic Potential of Cheese-Enamel Demineralization"	$42,000
Forrest W. Thye, Ph.D. Virginia Polytechnic Institute & State University "Effect of Protein Source and Calcium Level on Plasma Lipids, Blood Pressure and Mineral Utilization in Men"	$35,000

ATTACHMENT B

Dairy Food Value Print Coverage
(December, 1984 - April, 1985)

Young Women (12-24)	
CO-ED	January February March April
COSMOPOLITAN	January February April
GLAMOUR	January February March April
MADEMOISELLE	December February March
PEOPLE	January 7 February 11 March 11 April 15
SCHOLASTIC	February March
SELF	December February April
SEVENTEEN	January February March April
TEEN	January February March April
YOUNG MISS	December January- February March April

Adult Women (25-49)	
AMERICAN HEALTH	December January- February March April
BETTER HOMES & GARDENS	January March April
FAMILY CIRCLE	February March April
GOOD HOUSE-KEEPING	December March
HEALTH	January February March April
McCALL'S	December January March April
NEWSWEEK	February 4
NEWSWEEK WOMAN	December 24 February 25 March 25 April 22
PEOPLE	January 14 February 18 March 25 April 22
REDBOOK	March April
SHAPE	January February March April

Adult Women (cont'd)	
TIME	Feb. 11
WOMAN's DAY	January March April
WOMEN's SPORTS AND FITNESS	January February March April
WORKING WOMAN	February March April

Mature Women (50+)	
MODERN MATURITY	Feb-Mar April-May
READER'S DIGEST	March April
50+	March April
GOOD HOUSE-KEEPING	February April
LADIES HOME JOURNAL	February March April
DYNAMIC YEARS	Mar-April

A CLINICIAN'S APPROACH TO THE PREVENTION OF OSTEOPOROSIS

Morris Notelovitz, M.D., Ph.D.

Founder and Director of
The Center for Climacteric Studies, and
Professor in Obstetrics and Gynecology at
The University of Florida College of Medicine
Gainesville, Florida

INTRODUCTION

Osteoporosis has been appropriately described as a "silent epidemic" - one out of every four white women over the age of sixty-five can anticipate becoming a victim of osteoporosis, yet few will experience any symptoms prior to suffering an atraumatic vertebral, hip or wrist fracture - a characteristic of this disease. The cost, both in personal suffering - physical and psychologic pain - and in financial terms has been well-established. Osteoporosis has been ranked by the National Institute of Health as one of the three main reasons for long-term nursing home care.

Osteoporosis is a complex disorder; it is not even known why certain women develop the condition. Yet, there are two simple principles which, if adhered to, could prevent osteoporosis:

(1) Women need to acquire as much bone as possible before the onset of the menopause.

(2) The natural rate at which bone is lost needs to be controlled.

This goal may be cost-effectively achieved by meeting three objectives:

(1) Educate the consumer and health care professionals about osteoporosis and osteopenia. This can influence persons at risk to modify their life-styles and to exclude unnecessary "at risk" practices, e.g., excess caffeine usage and smoking.

(2) Evaluate and develop methods of screening for osteopenia. Osteopenia may be regarded as a pre-condition to osteoporosis. It is characterized by low bone mass without overt fractures and is a potentially reversible condition. Regular x-rays are too insensitive; a loss of 30% in bone mass is needed before osteopenia can be detected by this method. Newer techniques - single and dual-photon absorptiometry - if appropriately and

intelligently utilized, together with clinical evaluation and judgement, can be usefully employed to aid in the selection of those women at higher risk and thus in need of specific treatment.

(3) Encourage - from late adolescence and early adulthood - the promotion of increased bone mass and strength by both regular weight bearing exercise and appropriate nutrition and, for those women who undergo an early menopause or who are rapid bone losers, the selective and judicious use of combination hormone therapy - estrogen and progesterone. Since other therapies are also available, tests that can monitor an individual's response to the above "basic" therapy, would be most helpful; non-responders could thus be readily identified and placed on alternative treatment.

THE CENTER FOR CLIMACTERIC STUDIES' OSTEOPOROSIS PREVENTION PROGRAM

EDUCATION PROGRAM: A recently completed study, initiated eighteen months ago, set out to determine the knowledge level of unselected women attending four different types of medical practices in the Gainesville area - a group family practice; a female gynecologist; a male gynecologist and a public health department. Women were contacted by letter and responders sent an educational packet, followed at six-monthly intervals by a seminar on osteoporosis and a free densitometry evaluation. Repeat analysis eighteen months after the initial interview revealed that of the 418 women who completed the study, sixty percent had changed their life-style directly

as a consequence of this intervention.

The knowledge level concerning osteoporosis improved in all categories tested (see tables 1 and 2). Based on normative data provided by the manufacturers of our rectilinear scanner, 72.2% of the subjects (who were all white and mainly from a middle class socioeconomic group), had average or above average bone density, while 27.8% had low average density. Irrespective of the status of the bone mass result, the performance of the tests resulted in a significant improvement in the subsequent knowledge level.

OSTEOPENIA SCREENING: The utilization of certain radioactive isotopes in specially designed instruments has allowed for the precise measurement of the bone mineral content of regions of the skeleton at high risk for osteoporosis. With single photon absorptiometry, it is possible to measure the bone mineral content of the mid-shaft of the radius (representing mainly cortical bone found in the long bones) and at the far-distal (wrist area), a mixture of cortical and trabecular bone. The latter is found primarily in the spine - the commonest site of osteoporosis. Measurements are either made at one point or over a one centimeter area (rectilinear scanning). Use of a different type of isotope allows instruments known as dual photon absorptiometers to assess the bone mineral content in deeper regions of the skeleton - vertebrae and hip or the whole skeleton.

The advantage of the above techniques include safety, low radiation exposure, non-invasive technique, and ease of performance. Other methods, e.g. computer tomography, are also very effective but have the disadvantage of a greater radiation dose, cost and non-availability of instruments. Dual energy CT scanning is probably the most sensitive and reproducible technique available.

At the Climacteric Center, both single and dual-photon absorptiometers have and are being evaluated to see if they can aid in: (a) detecting asymptomatic osteopenia, and (b) monitoring response to preventive measures and/or specific therapy. Various programs were initiated in August 1981 and include a trial clinical service, a mobile unit used to screen for osteoporosis in outlying areas and various clinical research studies. The following has been our experience to date.

Single-Photon Absorptiometry:

Single point analysis:	2,023 women were seen on the clinical service.
:	536 women participated in the mobile unit screening program.
Rectilinear scanning:	619 women were evaluated.

Dual-Photon Absorptiometry:

Lower (lumbar) spine scanning:	260 women
Total body scans:	385 individual tests
	1,200 repeat tests

PRACTICAL APPLICATIONS:

(1) Screening: Based on this experience, we have developed a clinical program that utilizes single-photon absorptiometry as a means of screening for persons with osteopenia. This measurement correlates fairly well with the total body calcium and allows one to differentiate individuals with normal and low bone mass. Based on a comparison of the two techniques, reliance on the single-photon absorptiometry result alone would have resulted in our missing twenty percent of women with osteopenia. However, we detected eighty percent who would have been unaware of their potential problem. As will be noted later, the applicability of the test is enhanced by taking other clinical features into consideration.

Women with osteopenia and/or those with added significant clinical features are advised to be further evaluated with rectilinear scanning of the arm (to assess cortical bone status), dual-photon absorptiometry of the lower spine (to assess the trabecular bone status), a biochemical profile and a urine test that indirectly evaluates calcium loss from the skeleton.

The initial screen - which may be compared with a pap smear in terms of its objective of identifying a risk of disease rather than a definitive diagnosis - costs $30.00 to $50.00. The second tier level of testing, which is applicable only to those with an existing and identified medical problem (osteopenia) costs $250.00 to $300.00. Our experience has shown that this would involve about twenty-five to thirty percent of white, perimenopausal women. To enhance the cost-effectiveness of any screening program, women at high risk should be the primary target. A high risk osteoporosis profile includes: white and oriental women, petite stature with narrow bones; blond complexion; early menopause; family history of osteoporosis. Our results were based on an unselected population.

(2) Deciding on Hormone Therapy: Densitometry evaluation also allows physicians to be more objective when deciding on hormone replacement therapy. An otherwise healthy woman who enters the menopause with low bone mass would be a candidate for hormone therapy, whereas a woman with normal bone mass might not. Unnecessary cost and potential side effects from hormone therapy may thus be avoided.

(3) Monitoring Treatment: A less reliable application of the technique has been to monitor the response of patients to their treatment. This is due to variations in positioning and reproducibility with

some methods, but is less so with single-photon rectilinear scanning and dual-photon absorptiometry evaluation of the lumbar spine. Repeated tests (e.g. at six-monthly intervals) over a two year period will frequently give a good quantitative result well before other available diagnostic techniques. Fortunately, osteoporosis is a slowly developing condition so a two year time frame is not an unreasonable period for observation and adjustment of treatment.

LIMITATIONS OF THE TECHNOLOGY

(1) It is important to appreciate that densitometry evaluates only one possible reason for bone fractures; a deficiency of bone mineral (calcium). A lack of calcium does not necessarily mean that fractures will occur, nor conversely, that an adequate calcium content precludes fractures. Other factors, such as bone protein and elasticity, and a tendancy for some women to fall, may be equally important.

(2) Adjacent tissues that contain calcium, e.g. arthritic changes in joints, calcification of the arteries next to bone, may artificially increase the bone mineral content value. This is especially true for lumbar dual-photon absorptiometry.

(3) Normative values need to be clearly defined and be based on instruments placed and used in the marketplace. Regional differences may also be relevant. For example, women from Wisconsin who are exposed to less sunshine, may have appreciably lower values than matched women from the Sunshine State. We have found that the normative range for women in our area to be ten percent lower than in women in Scandinavia. Unless the test results are based on appropriately collected and collated data

from well-defined normal populations, the technology cannot be expected to yield consistently meaningful results.

(4) Application of the data to a given subject, necessitates more than a mere performance of the test. The technologist needs to be well trained and capable of evaluating the applicability of the test result during its performance and to make whatever corrections and/or adjustments are appropriate at that time. A medically qualified supervisor should be available for consultation.

(5) Reporting a bone mineral content result may of itself be meaningless and may even be confusing. Other aspects regarding the patient's history and examination (including other tests, if necessary) need to be taken into consideration before a constructive and meaningful opinion can be given to the patient and, where applicable, her referring physician. To optimize this technology, health care professionals should be educated, trained and have a specific interest in osteoporosis diagnosis and treatment.

(6) Clinical judgement and care must be exercised when extrapolating data measured in one area of the skeleton to another region. This is as true for our program of screening (mid-shaft radius and total body calcium) as it is for dual-photon absorptiometry and CT scanning (measurement of the bone mineral content in the lumbar spine, although the usual area for fractures is in the mid to upper thoracic vertebrae).

CONCLUSIONS

Based on our own research, clinical experience and a review of the literature, it is my firm conviction as a gynecologist specialized in

Climacteric Medicine, that the quality of life for women during the mid and later years can be immeasurably enhanced by relatively simple measures such as education and life-style change. This is especially true for osteoporosis prevention. In this context, single and dual-photon absorptiometry are important aids in our armamentarium, but need to be applied intelligently and selectively in clinical practice by persons who are trained and knowledgeable about the condition they're attempting to prevent.

Recommended Reading:

The Pathogenesis and Treatment of Involutional Osteoporosis

C. Nagant de Deuxchaisnes in Osteoporosis, A Multidisciplinary Problem. Ed. A. St. J. Dixon; R.G.G. Russel and T.C.B. Stamp. The Royal Society of Medicine; London, pages 291-333.

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Table I

Percentages of Subjects Responding Correctly to General questions on Incidence, Risk and Signs of Osteoporosis

(n=418)

Item	Group 1 After (Before)	Group 2 After (Before)	Group 3 After (Before)	Group 4 After (Before)	Total After (Before)
Women aged 50 years or older at very high risk	59.1 (54.6)	70.9 (69.9)	72.8 (70.9)	73.3 (71.9)	71.8 (70.1)
One in every four women will develop osteoporosis	40.9 (13.6)	38.8 (23.3)	34.2 (18.4)	47.4 (16.3)	39.6 (19.1)
There are no early warning signs	68.2 (45.5)	73.8 (47.6)	77.2 (51.9)	75.6 (49.6)	74.4 (49.8)
Visible signs	68.2 (40.9)	81.6 (65.1)	84.8 (62.7)	88.9 (70.4)	84.5 (64.6)

Table II

Percentages of Subjects Understanding
Roles of Risk Factors
(n=418)

	Group 1 After (Before)	Group 2 After (Before)	Group 3 After (Before)	Group 4 After (Before)	Total After (Before)
Overweight ↓	40.9 (18.2)	39.8 (26.2)	47.5 (26.6)	52.6 (20.0)	46.9 (23.9)
Fair Complexion ↑	40.9 (4.6)	42.7 (8.7)	48.1 (12.7)	58.5 (15.6)	46.8 (12.2)
Pregnancy ↓	45.5 (9.1)	26.2 (32.0)	27.8 (22.2)	37.0 (23.7)	31.3 (24.4)
Alcohol ↑	50.0 (18.2)	59.2 (31.1)	53.8 (20.3)	63.7 (28.2)	58.1 (25.4)
Exercise ↓	68.2 (54.6)	69.9 (54.4)	79.1 (60.8)	79.2 (57.8)	76.3 (57.9)
Menopause ↑	77.3 (59.1)	79.6 (66.0)	81.0 (73.4)	85.2 (74.8)	81.8 (71.3)
Calcium ↓	86.4 (45.5)	79.6 (67.0)	87.3 (69.0)	88.9 (68.2)	85.9 (67.0)
Vitamin D ↓	54.6 (27.3)	65.1 (47.6)	56.3 (44.9)	60.7 (43.7)	59.8 (44.3)
Smoking ↑	59.1 (27.3)	63.1 (35.9)	63.9 (30.4)	73.3 (33.3)	66.5 (32.5)
Family History ↑	59.1 (27.3)	66.0 (55.3)	77.9 (56.3)	81.5 (63.7)	75.1 (56.9)
Beef/Pork Consumption ↑	22.7 (0.0)	36.9 (16.5)	27.8 (9.5)	29.6 (11.1)	30.4 (11.2)

↑increases risk
↓decreases risk

THE CENTER FOR CLIMACTERIC STUDIES AND CLIMACTERIC MEDICINE: A BRIEF OVERVIEW

The climacteric is a natural and inevitable event.

The climacteric is the medical term for the middle years - arbitrarily defined as the interval between age 35 - 65 years. During this time, a number of changes occur in women directly as a consequence of aging of the ovary, and the eventual cessation of hormone production. One such change is the menopause - the last natural menstrual period - and hot flashes. Both are characterized as the badge of the "change of life", but neither poses a health hazard. More important are subtle and progressive changes that occur e.g. in bone and blood vessels, and which if unrecognized, can progress to osteoporosis and cardiovascular disease. Both have a significant impact on the quality and quantity of life.

Climacteric medicine is a discipline waiting to be born. In short, it may be defined as preventive medicine for women (and men) in the middle years, and has its basic premise, consideration of the individual as a whole, with the objective of achieving a healthy mind, in a healthy body, in a healthy environment.

To achieve these goals, a multidisciplinary program was developed with the establishment of the Center for Climacteric Studies at the University of Florida in April, 1980. A team approach to the overall health care needs of the individual is encouraged: routine medical care is complimented by nutritional advice, stress management and psychologic counseling, exercise prescription, selective hormone usage, advice regarding careers in the home and in the workplace, and the provision of educational opportunities. The latter is in many respects the most important feature of our program. The reality and consequences of the climacteric is spelled out to women before they experience their menopause and accompanying hot flash.

Fear of the unknown is defused similar to that achieved by childbirth preparation classes. Our program is, in fact, sometimes referred to as the "Lamaze of the Middle Years."

The climacteric occurs chronologically at a time when aging, of itself, results in conditions such as diabetes and cancer, neither of which are directly related to the climacteric. However, by the early institution of simple and inexpensive lifestyle rules - sensible nutrition, exercise, avoidance of habits such as smoking and alcohol abuse - many of the costly "consequences" of aging - osteoporosis, cardiovascular disease, urinary incontinence, cancer and diabetes, may be prevented or significantly ameliorated.

The development of newer technology aids in this process: densitometers for the early detection of osteoporosis; stress and treadmill tests to determine cardiorespiratory fitness; mammography for breast cancer detection; urodynamics to determine the cause for urinary incontinence; biofeedback technology to aid in stress management, etc. Complimented by specially trained health care professionals, this technology can be productively used to ensure the goal of quality life for middle-aged men and women.

Climacteric Medicine is, in some respects, a national insurance policy. A healthy middle-aged population will be a productive population; by preventing or ameliorating chronic illnesses such as osteoporosis, much of the cost of long-term geriatric care can be avoided. We have noted the benefit of preventive medicine in obstetrics and dentistry. Why should the climacteric be any different?

Since its inception five years ago, the Center for Climacteric Studies has established a central and leading role in both national and international medical circles concerned with menopause practice and research. More specific information on the Center is available.

UPDATE OF SINGLE VS. DUAL PHOTON DENSITOMETRY

by

Walter D. Reese, M.D. 6/14/85

Post menopausal osteoporosis has received a great deal of publicity in the past year, and rightfully so,not only because it is one of our biggest public health problems, but also because the troublesome phase of the disease has been proven to be preventable. The constantly increasing life expectancy of our population is expected to exaggerate the frequence of fractures in the elderly, unless aggressive, preventive measures are taken. Voluminous literature is directing attention toward prevention through improving calcium intake, recommending exercise programs and most of all advocating long term estrogen replacement therapy. It is now well known, and well discussed that the petite, thin, light skinned, non athletic post menopausal female who drinks and smokes is considered to be the woman at great risk for developing osteoporosis. This description is not enough - she must be diagnosed. Diagnostic screening is available, is necessary and should be quite effective, since we can take advantage of the ten to fifteen year latent phase that proceeds the fracture phase of the disease; but physician progress in recommending screening has been disappointing.

SCREENING AND DIAGNOSIS

The above description of the woman at risk is helpful to the clinican, but is insufficient evidence both for screening and diagnostic purposes, and can be very misleading in many cases. A number of non-invasive diagnostic methods have been developed over the past twenty years, the oldest and most tested of which is single beam photon absorptiometry. Other non invasive methods include computed tomography, whole body nutron activation analysis and dual photon absorptiometry of the vertebral spine and hip. Except for single beam densitometry, the other techniques mentioned cannot be considered good screening meth-

ods by reason of excessive cost and/or excessive radiation. Single photon densitometers are commercially available, mobile, relatively inexpensive and are a time tested and proven method of screening bone density with the lowest patient cost. In addition, the roentgen exposure is not a problem: it is approximately 1% of that received through an x-ray picture. Single beam densitometry however, is limited to screening bones with relatively light tissue cover, such as the forearm, hands or heel bone. The heavy fat cover of the vertebrae and hips, which are of course, common fracture sites in osteoporosis, eliminates the single beam densitometer from scanning these areas. Intramedullary vertebral fat and body fat of uneven density, however, also interferes with the precision, accuracy and reproducibility of computed tomography and dual beam densitometry. Compared to single beam densitometry, these methods aren't as cost effective or practical for developing diagnostic information, and should be considered research and diagnostics aids.

Considerable controversy among researchers has arisen as to the value of comparing very accurately measured cortical bone of the mid radius, using the single beam densitometer to the trabecular bone of the vertebrae using dual beam densitometry or computed tomography. It is obvious that composition of the trabecular bone of the distal radius should be more comparable to the trabecular bone of the vertebrae; and thus, a better screen for the very common crush fracture syndrome. Until recently, however, the tapering effect of the distal radius where trabecular bone predominates has been almost impossible to reproduce with acceptable accuracy. The less tapering mid radial site, because of its uniform diameter, was thus chosen,originally because of very favorable reproducibility and accuracy. This mid radial site compares more favorably with the bone density of the hip and total body calcium, but less favorably with the vertebral bone density than is desired.

Because of a new method, the tapering bone problem of the distal radius is past history, and the more desirable trabecular bone screening of the distal radius now correlates very closely with the trabecular bone of the vertebrae, according to researchers from the division of orthopedics and the division of imaging of the University of North Carolina School of Medicine. In the past fourteen months, I have had frequent communications with Dr. Talmadge, one of the developers of the new technique, and have performed several hundred scans that to date, have proven very satisfactory in accuracy and reproducibility. I have confirmed that the repeatability in serial measurements of the new distal radius site carries less than a 2% error, whereas the error of reproducability of the "old distal (10%) site" was 7 to 12%, an error that is unacceptable for following the effect of treatment programs.

Several new densitometers utilize an improved rectolinear scan of the distal radius and ulna and of the "ultra distal" site with only a 1% repeatable error. In addition, a new single photon densitometer applies rectolinear scanning to the os calsis, a site of extremely high (95%) trabecular content. An earlier recognition of gain or loss from treatment because of the more rapid remodeling of trabecular bone is thus promising, as well as offering better prediction of fracture risk.

Over the past several years, single photon absorptiometry has been unfairly denounced by one un-named flamboyant researcher in particular, who favors dual photon absorptiometry. Through his prolific writing and lecturing, his bias against single photon and his bias for dual photon absorptiometry is obvious to "single beam" enthusiasts, not only in te United States, but internationally . His efforts to have dual photon absorptiometry, approved for reimbursement by Medicare, the Blues and other third party carriers is laudable, but it should not undignify or be damaging to the respected image of single photon absorptiometry.

It is puzzling to me, and to many of my colleagues that this highly respected researcher continues to manufacture and sell good single photon densitometers,while he aggressively markets his dual photon instrument by condemning single beam technology. We could praise his aggressive dual photon marketing approach if it were not damaging the long needed momentum of the early diagnosis and aggressive management of osteoporosis. Through his actions, loosing the approval of Medicare Reimbursement for the mor practical and less expensive single phton densitometry could occur. A more practical and recommended solution would be to recommend the deserved approval of dual photon absorptiometry for additional diagnostic testing, rather than its present approval for research and to retain the present reimbursement status of single photon densitometry.

Copenhagen
International
Symposium on
Osteoporosis
June 3-8, 1984

DIFFERENT RATES OF LOSS OF TRABECULAR AND CORTICAL BONE AFTER THE MENOPAUSE.

L. Hilas, J. Borg and C. Christiansen

Department of Clinical Chemistry, Glostrup Hospital, University of Copenhagen, Denmark.

The aim of the present study was to examine the rate of bone loss from trabecular and cortical bone by measuring bone mineral content with single photon absorptiometry in the distal part of the forearms. We normally express BMC in the forearm as the mean of 5 scans 4 mm apart with the first scan obtained at the site where the distance between the ulna and radius is 8 mm. This method has a reproducibility of 1%, and the BMC is closely related to bone mass in the whole skeleton. We have now extended the scan procedure with 4 additional scans distal of the start point, measured with a distance of 2 mm. Furthermore, BMC spine was measured with dual photon technique.

Participants: 57 premenopausal and 20 postmenopausal women, 5 years after the menopause.

Results:

	Most distal scan BMC (units)	Most proximal scan BMC (units)	Spine BMC (grams)
Premenopausal	42.9 ± 6.0	42.2 ± 4.7	46.5 ± 7.1
Postmenopausal	35.5*** ± 7.7 (83%)	39.1° ± 6.1 (93%)	38.7*** ± 7.3 (81%)

Values are given as mean ± SD; *** = $p < 0.001$; ° = $p < 0.05$ vs premenopausal women.

In the postmenopausal women the BMC fell from the most proximal to the most distal scan site ($p < 0.001$), whereas no difference between the first and last scans were seen in the premenopausal women. In the postmenopausal women bone loss from the spine corresponds to bone loss from the most distal scan site, which contains the greatest amounts of trabecular bone.

Conclusion: The present data indicate that it is possible to measure rates of bone loss in trabecular and cortical bone with an easy and cheap technique. Five years after the menopause the bone loss is greatest in the spine and at the most distal scan sites. This indicates that the early postmenopausal bone loss mainly takes place from trabecular bone.

Different Rates of Loss of Trabecular and Cortical Bone after the Menopause

L. Nilas, J. Borg and C. Christiansen,
Department of Clinical Chemistry, Glostrup Hospital, Denmark

AIM:

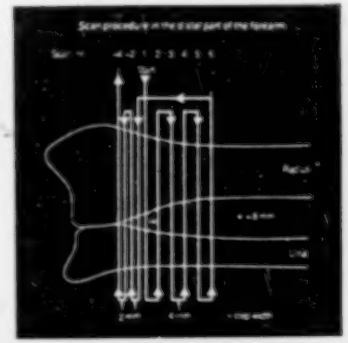
is to develop a simple method for measurments of bone mass and rates of bone loss in trabecular and cortical bone

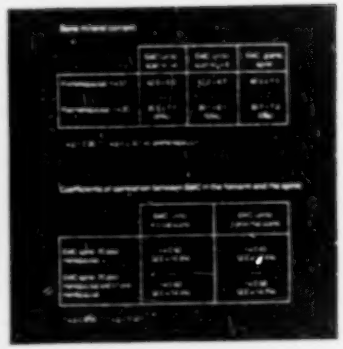
Participants

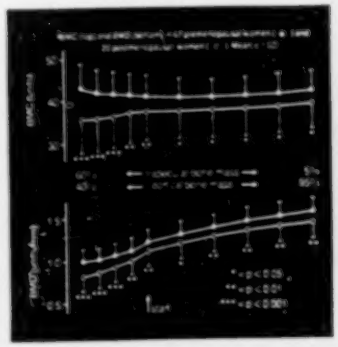
57 premenopausal women aged 45.0 ± 7.3 years and 20 women who had passed a natural menopause 5.5 ± 0.7 years ago, aged 53.0 ± 0.6 years

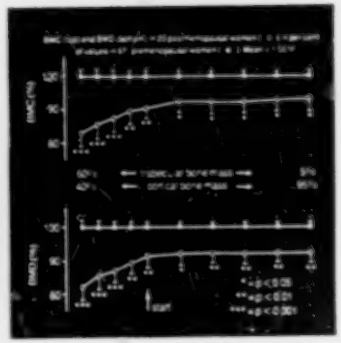
Methods:

BMC is measured with single photon technique and BMD is calculated as BMC divided with thquum of the widths of radius and ulna. In the spine BMC is measured with dual photon absorptiometry









Conclusion:

5 years after the menopause women have lost a considerable amount of bone. The greater losses in the lumbar spine and the most distal part of the forearm suggests that the bone loss in the first years after the menopause mainly is from trabecular bone. The present data indicate that it is possible to measure rates of bone loss from trabecular and cortical bone with an easy and cheap technique

Fall Injuries in the Elderly

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[illegible]

Summary

Injuries are the sixth leading cause of death in the 75-and-over population, with falls the leading source of injury-related deaths. For every fall that is the underlying cause of death, there are almost 20 that result in a fracture of the hip. Eighty-four percent of hospital admissions for hip fractures occur in the 65-and-older population. The average length of stay in a short term hospital, 21 days, is almost double the average length of stay for all other causes in this age group and longer than the stay for any other diagnosis. The cost of new hip fractures in 1980 was estimated to be 2 billion dollars.

Hospitals and residential centers for the elderly have high rates of falls and injuries among the elderly. With increasing age, there is a corresponding increase in the proportion of fatal falls that occur in nursing homes, i.e., 1 in 5 for ages 85 and older. The high death rate from falls in the elderly can be attributed to decreased ability to perceive and respond to hazards, a lower injury threshold (especially related to osteoporosis), and complications following injury. The patterns of reduction of injury mortality in the past two decades are likely to be the result of our medical and trauma care system's impact on the outcome of less severe injuries. Major improvements in the future will come through preventing hip fractures.

Injuries are the sixth leading cause of death in the 75-and-older population (16), with falls the leading source of injury-related deaths (Figure 1). Each year there are about 9,500 deaths among people age 65 or older in which a fall is given as the underlying cause of death; the number of cases where a fall initiates or contributes to a chain of events that culminates in death is probably even greater (1).

For every fall that is the underlying cause of death, there are almost 20 that result in a fracture of the hip. This single diagnosis is the most common one among all injuries (in all age groups) leading to hospital admission in the U.S. (10). Of some 200,000 hip fractures each year, 172,000 or 84% occur in the 65-and-older population. Although hip fractures do not appear in the NCHS ranking of the 20 most common Diagnosis-Related Groups among people 65 years of age and over, only 10 DRGs cause more hospitalizations in this age group (18). (Apparently, the Diagnosis-Related Group partitioning of hip fractures by age groups, procedures, etc. obscures the magnitude of the problem.)

Each hip fracture results in an average stay of 21 days in a short term hospital. This is almost double the average stay for all other causes in this age group, and longer than

the stay for any other diagnosis.

Not only hip fractures but other fractures of the extremities increase markedly with age (Figure 2) (1). The toll taken by these injuries -- many of which lead to decreased mobility, reduced independence, and major changes in life style, cannot be readily measured. The cost of new hip fractures in 1980 was estimated by Robinson to be 2 billion dollars (19).

The estimate is based on the direct cost of hospital and nursing home stays and physician's and surgeon's fees for 172,315 medicare and 5,169 non-medicare covered hip fractures and the indirect costs of lost productivity. The latter includes the loss of housekeeping services and wages for those elderly still gainfully employed. Follow-up and rehabilitation costs for future years are not included:

Medical costs	$1,546,782,000
Indirect costs	$ 355,288,000
Future costs	222,222,222
	$1,992,060,000

RATES OF FALLS IN INSTITUTIONS

With increasing age, there is a corresponding increase in the proportion of fatal falls that occur in residential institutions such as nursing homes; for ages 85 and older, this proportion is about one in five (1). Not only are there about 1,800 recorded fatal falls that occur annually in nursing homes, but such facilities have high rates of falls and of fall injuries.

In one such facility, we are currently studying the high-risk patients and the circumstances of falls and injuries. The goal of this research is to identify personal and environmental factors related to falls and injuries in order to develop and test a screening tool that staff in nursing homes and geriatric care facilities can use to predict those patients at greatest risk of falling and of sustaining serious injury.

The rate of falls in this nursing home is approximately 2000 per 1000 patient years, or 2 per patient per year. Patients in this geriatric facility, where the average patient census is 270 people and the median age is 82, have experienced 1078 falls and 16 hip fractures in the past 2 years. In terms of the injuries sustained in the fall, 2.4% of the falls resulted in hip and other fractures. Females who fell were 7 times as likely to fracture a hip as males. Clearly this represents not only a serious problem for the patients, but a sizable and costly problem for the institution.

Similarly, hospitals and residential centers for the elderly also have high rates of falls and injuries. Gryfe, Amies and Ashley (9) found an annual fall rate of 668 incidents per 1000 among an active ambulatory institutionalized population over 65 years of age. Rohde has studied retrospectively falls and injuries at The Johns Hopkins Medical Institutions and has found the overall rate of falls to be 30 per 10,000 patient days, for patients 65 years and older (45 for males and 54 for females)

(22). In view of the advanced age of many patients in such institutions and the presence of underlying medical and physical conditions that may contribute to the incidence of falls and fractures, this is not surprising. In addition to age, several factors related to falls among the institutionalized elderly have been reported in the literature. They include: sex, family status, mental status (12), the number of chronic conditions present and alcohol consumption (26), the onset of acute disease (20), impaired functional capacity (15,23), micturition syncope (23), cardiac arrhythmias and acute cardiac changes (7,8). Disturbances of the mechanisms of balance, which may predispose the elderly to falls, may be related to perception (vision, vestibular function, proprioception), control (transient circulatory insufficiency and toxic, metabolic, or anoxic impairment of gait), and effectors (diseases of the peripheral nerves or muscles) (28). The presence of populations where the risk of injury is extremely high means that at such institutions there would be especially great payoff for measures that reduce the number of falls or the likelihood of injury when falls occur.

There is evidence of increased efforts by health professionals and managers of institutions with populations of elderly patients or residents to identify high risk individuals and implement preventive measures (3,11,13,17).

EPIDEMIOLOGY OF INJURIES

Before discussing some of these measures, a closer look

at the epidemiology of fall injuries is in order. When any group of people has an especially high death rate from a particular injury or disease, the reasons for the high death rate can be classified under one or more of the following three groups of factors:

1. Greater exposure to the etiologic agent
2. Lower threshold --i.e., greater susceptibility to the injury or disease
3. Greater likelihood of a fatal outcome, once the injury or disease occurs

High rates of fall injuries and deaths in the elderly are a function of factors in all three categories. The etiologic agent in fall injuries is mechanical energy. Potential energy is converted to kinetic energy when the body experiences a change in elevation. When the change is abrupt and the forces are not sufficiently gentle and evenly distributed over the body, we speak of an "impact" -- not unlike the impact of a car occupant in a crash, hitting the relatively stationary instrument panel or steering wheel.

EXPOSURE

For many reasons, the elderly are at increased risk of falling and, thereby, of being exposed to the mechanical energy of an impact. Decreased vision makes it hard to discern the presence or location of obstacles in their paths, or even of the chairs they intend to sit down in. A variety of sensory

limitations and medical problems, including postural hypotension, contribute to poorer balance. Failure to raise the foot sufficiently high with each step adds to the likelihood of tripping. Poorer reflexes and reduced strength make it difficult to recover ones balance if a fall is initiated. These and other factors -- including problems created by canes, walkers, and wheelchairs (4,26) -- contribute to the high rate of falls. Outside the scope of this paper is the possibility that some falls are precipitated by a fracture of the hip. While such "pathological fractures" no doubt occur on occasion, their incidence has never been measured and their importance may well be exaggerated.

LOWER INJURY THRESHOLD

Susceptibility to injury, due to a lower injury threshold, also increases in the elderly. In particular, the fragility of bones and their liability to fracture when exposed to a specified force increases with age-related osteoporotic changes. Although osteoporosis is more common in females than in males, both sexes experience a marked age-related increase in osteoporosis and in fracture rates. For ages 75-84 and 85+, the incidence of hip fractures among males is about half the rate for females; both sexes experience roughly a 10-fold increase in the rate of hip fracture during the intervening decade of life (1).

Susceptibility to injury may be affected by the medications the elderly person is receiving by lowering or changing the injury threshold. Medications reported to be related to falls

include psychotropic drugs (2,5,24), barbiturate use (14), and antihypertensive therapy (5).

DEATH RATES

The importance of age-related factors in determining survival, once an injury has been sustained, is illustrated by comparing death rates from falls with the incidence of fall injuries seen in emergency rooms. In females age 75-84, for example, the death rate from falls is almost five times as high as at age 65-74 (1). The injury rate, on the other hand, is less than twice as high as at age 65-74 (Figure 3) (6). Thus, the ratio of fall deaths to injuries more than doubles in this period. In males, there is a similar increase in the case fatality rate.

Thus, advancing age is associated with a poorer outcome following injury; the rib fracture or other injury that might be trivial in a younger person may eventually require hospitalization and even prove fatal in an older person, especially one with underlying medical problems or reduced mobility. The patterns of reductions in fall injury death rates during the past two decades, with greater reductions among infants and the elderly, suggest that our medical and trauma care system may have had its greatest impact on the outcome of less severe injuries, that are rarely fatal in the immediate post-trauma period (1). Additional support for this hypothesis comes from the change in the sex ratio of death rates from falls. In 1960, the rates were substantially higher for elderly females. Since then, female death

rates have decreased more than the rates for males (1), whose deaths are more apt to involve severe head injuries. By 1980, female death rates from falls were lower than male rates for all ages, even though fall injury rates are substantially higher for females after age 40 (Figure 3).

While reductions in fall mortality during the past two decades may primarily reflect advances in medical care, our prediction is that major improvements in the future will come about through preventing hip fractures. Strengthening the bone by preventing or slowing osteoporotic changes is one approach that will someday be a reality. In care-giving facilities such as hospitals and nursing homes, advances will come through increases in our ability to identify patients who are at greatest risk of hip fracture and then modify their immediate environment and increase monitoring and staffing. In homes as well as public facilities, progress is needed in environmental design; attention to walking surfaces, stairs, railings, lighting, and the design of beds and chairs has the potential to markedly reduce the incidence and severity of falls.

Most of the basic knowledge and technology needed for environmental changes is available but not applied. To cite just one example, handrails that can easily be grasped are a well-established design principle (25) -- but hand rails that are very difficult to grasp are the norm in two of the three nursing homes we have visited most recently, in many shopping

centers and public facilities, and even in some schools of public health.

There is no major health problem where the potential for improvement exceeds that for fracture of the hip. Hopefully that potential will soon be realized, so that our generation and those that follow us will not be subject to the same likelihood of morbidity, disability, and tragic changes in lifestyle that today are associated with falls in the elderly.

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Figure Legends

Figure 1 Deaths per 100,000 Population by Age in 1977

Figure 2 (Source: Reprinted with permission from: Baker, S., O'Neill, B., Karpf, R. The Injury Fact Book, Lexington Books, Lexington, MA, 1984.)

Short-stay Hospital Discharge Rates for Fracture of the Hip and All Other Fractures by Age and Sex, for Ages 65 and Older, NCHA Hospital Discharge Survey, 1980.

Figure 3 Fall Injury Rates Per 1000 Persons. (Adapted from: D. Fife, J.I. Barancik, and B.F. Chatterjee (1894): Northeastern Ohio Trauma Study II: Injury Rates by Age, Sex, and Cause, Am. J. Public Health, 74:473-478).

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Editorial:

Bone of Contention

Osteoporosis and secondary fractures of the lumbar spine and hip account for significant pain and disability. The cost of short-term care in the United States of this complication exceeds $1 billion annually. The fall meeting of the Central Chapter of the Society of Nuclear Medicine will deal with metabolic bone disease in orthopedic nuclear medicine. A full day is devoted to bone mineral analysis.

In recent months, there have been several reports in both the general and nuclear medicine literature using dual photon absorptiometry for the measurement of lumbar spine bone mineral density. Mazess et al (*1*) reported on the superiority of the dual photon method over single photon absorptiometry for the assessment of lumbar spine mineral content. Drinkwater et al (*2*) found vertebral mineral density to be significantly lower in a group of young amenorrheic athletes with lower estradiol and progesterone levels. There were no differences in radial bone measurements. Dual photon absorptiometry technique uses a radioactive source (gadolinium-153) with dual energy peaks (44 and 100 keV) to determine bone mineral content and density while correcting for variable soft tissue thickness in the region of the lumbar spine. The gonadal radiation dose is approximately 2 mrads. Single photon absorptiometry using an iodine-125 source was used for many years to determine wrist bone density. While this latter method is useful as an indicator of overall skeletal status, it is relatively insensitive as an indicator of lumbar spine bone mineralization.

The Health and Public Policy Committee of the American College of Physicians (*3*) has concluded that although the relative value of dual photon absorptiometry and quantitative computed tomography has not yet been completely determined, the measurement of bone mineral density is of merit in the management of patients with metabolic bone disease. The dual photon method is preferable at this time because of its accuracy, precision, lower radiation dose, and cost.

Although there is no controversy within the scientific and medical community about the value of dual photon absorptiometry for the detection and management of disabling and costly lumbar spine collapse, the technique is not without controversy. Ongoing efforts by developers and manufacturers to obtain reimbursement for this examination has been stymied by the reluctance of the Health Care Financing Administration to provide such coverage because of an apparent misunderstanding of the ongoing discussion within the scientific community of the relative merit of the technique versus the more expensive computed tomographic technique. The Office of Health Technology Assessment would do well to recommend approval of these devices and reimbursement for this technique for the determination of lumbar spine mineral content.

References

1. Mazess RV, Peppler WW, Chesney RW, et al: Does bone measurement on the radius indicate skeletal status? *J Nucl Med* 1934;25:281-88.

2. Drinkwater BL, Nilson K, Chestnut CH, et al: Bone mineral content of amenorrheic and eumenorrheic athletes. *N Engl Med* 1984;311:277-80.

3. Health and Public Policy Committee, American College of Physicians: Radiologic methods to evaluate bone mineral content (Position Paper). *Ann Intern Med* 1984;100:908-11

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Bone Mineral Densitometry:

Society Responds to HCFA and Blue Cross/Blue Shield Subcommittee

"In the last few years, two methods, dual photon absorptiometry and quantitative computer tomography, have been developed with a great potential for use in general clinical practice. Of these two, dual photon absorptiometry is at this time the method of choice."

While patients requiring measurement of lumbar spine bone mineral density, and nuclear medicine physicians who provide this measurement, await the pronouncement of the Health Care Financing Administration (HCFA) on the appropriateness of reimbursing for dual photon absorptiometry, the Blue Cross/Blue Shield (BC/BS) Medical Advisory Subcommittee on September 5, 1984, recommended to its parent body that it disapprove claims submitted for single and/or dual photon absorptiometry.

Some BC/BS plans did reimburse for single photon absorptiometry before the September 5 decision. HCFA approved reimbursement for single photon studies about two years ago, but now that decision is also being reassessed. Except for a handful of state BC/BS plans, neither group has ever endorsed payment for dual photon absorptiometry.

Henry Ernstthal, executive director of SNM, has written to BC/BS citing the interest and expertise of SNM members. He urged that no decision be promulgated without first considering expert testimony from Society members. Karen Smith, manager of Technology Evaluation and Coverage at BC/BS, has indicated that input from SNM would be both desirable and reviewed with care.

Wahner reviews methods

In response to an earlier request for relevant information by the Office of Health Technology Assessment (OHTA), published in the *Federal Register* (Oct. 26, 1984), the Society asked SNM member Heinz W. Wahner, MD, of the Mayo Clinic's Section of Diagnostic Nuclear Medicine, to prepare a report on the efficacy and desirability of bone mineral measurement. Dr. Wahner has been active in the field for many years, and recently authored a two-part series on the subject (*1*).

In the SNM report, he stated that "numerous methods for assessing bone mineral have been used for the past 30 years. These procedures have advanced the knowledge of bone disease, but have had little impact on patient management. In the last few

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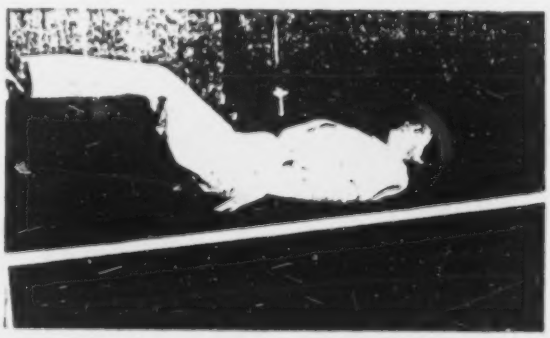

The vast majority of osteoporotic conditions affect trabecular bone, which is measured by dual photon absorptiometry of the lumbar spine (as seen above), although some disorders affect cortical bone, found in the distal radius and measured by single photon absorptiometry. (Courtesy of the University of Wisconsin)

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years, however, two methods, dual photon absorptiometry and quantitative computer tomography, have been developed with a great potential for use in general clinical practice. Of these two, dual photon absorptiometry is at this time the method of choice.

"The dual photon spinal scan is a reliable method to diagnose and follow patients with osteoporosis. The information given is not available from any other procedure with comparable accuracy, precision, acceptability to the patient, and for this relatively low cost," he concluded.

In an editorial entitled "Bone of Contention" (*Newsline*, Sept. 1984), Stanley J. Goldsmith, MD, director of nuclear medicine at The Mount Sinai Medical Center in New York, stated that "ongoing efforts by developers and manufacturers to obtain reimbursement for this examination have been stymied by the reluctance of HCFA to provide coverage because of an apparent misunderstanding of the ongoing discussion within the scientific community of the relative merit of the technique versus the more expensive computer tomographic technique." He added that "the Office of Health Technology Assessment (OHTA) would do well to recommend approval of these devices."

The dual photon method offers several advantages over computer tomography. It exposes the patient to less radiation—5 to 15 mrads for dual photon, as opposed to 200 to 1250 mrads for CT. The marrow is exposed to 500 times more radiation with CT than with the dual photon procedure. Whereas CT scanners cost $750,000 to $1 million, the dual photon bone scanner ranges from $35,000 to $40,000. The CT scan itself is also more expensive, about $300 to $400, compared to the dual photon bone scan which costs from $125 to $200, according to the nuclear medicine physicians contacted by *Newsline*.

Richard B. Mazess, PhD, associate professor of medical physics at the University of Wisconsin, and a pioneer in the area of bone mineral assessment, said, "The recommendation of Blue Cross/Blue Shield is incomprehensible to me." Dr. Mazess noted the irony of the BC/BS decision in light of a position paper published last summer by the American College of Physicians (ACP) which stated, "Dual photon absorptiometry (DPA) can be used to quantify changes in bone mineral content in patients who have metabolic bone disease, or who are undergoing treatment that alters bone content. If a test of bone mineral content is needed in the evaluation of patients with metabolic bone disease, DPA may be preferable at this time because of its lower radiation dose and cost." (*2*) When *Newsline* contacted the ACP about this issue, a public affairs staff member said that while the ACP did not advise BC/BS on this policy, a letter would be sent to "inquire of the Blues how and why its reimbursement policy was established."

"The marrow is exposed to 500 times more radiation with CT than with the dual photon procedure."

Since the BC/BS setback, Dr. Mazess said that the next step is to "mobilize opinion and mobilize the nuclear medicine community behind the efforts of the national leadership on this issue." He has pressured the OHTA several times over the past two to three years to move towards recommending that HCFA endorse reimbursement by Medicare and Medicaid for the dual photon procedure. Dr. Mazess is also the president of Lunar Radiation, a manufacturer of single and dual photon bone densitometers.

Ralph Robinson, MD, director of nuclear medicine and professor of diagnostic radiology at the University of Kansas, sent an extensive written argument to the Kansas City BC/BS in an effort to convince administrators that single and dual photon absorptiometry has "long since passed from the 'experimental' stage to assuming an active role in the management of patients with osteopenia from any of a variety of causes." His petition has been forwarded to the National BC/BS Association. Before the September 5 decision, BC/BS of Kansas City did accept claims for both these procedures, but the process is endangered by the recommendations of the national association.

Patients wary of cost

The ruling has made some patients at the University of Kansas hospital decide against further tests to monitor bone density. Dr. Robinson said that "the endocrinologist who refers some patients to this department believes that we're losing some follow-up and repeat studies because patients have found out that their initial study was not covered."

At the University of Cincinnati, Edward B. Silberstein, MD, associate director of the radioisotope laboratory, said, "I'm very upset about the recent Blue Cross/Blue Shield decision because there are a lot of women who are being deprived of an important test. One out of three women by

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age 65 can expect to have a fractured vertebra from osteoporosis. We need to find out who's at risk, and then we need to monitor the proper treatment. If we are prevented from doing that because of lack of third-party payment, we'll lose the chance to spare millions of women hospital admissions and a lot of pain."

Since this issue affects the elderly, Dr. Silberstein contacted Ohio Senator John Glenn, the ranking Democratic member of the Senate Special Committee on Aging. Senator Glenn sent a letter to HCFA early in December expressing his concern about "possible hindrances to the appropriate diagnosis and treatment of osteoporosis." He also noted that the disorder may be responsible for 1.3 million fractures a year, and cost an estimated $3.8 billion annually. The Senator concluded by requesting that HCFA review the letter from Dr. Silberstein about the problem.

The American College of Nuclear Physicians (ACNP) has also answered the OHTA's call for input, stating that the dual photon procedure "has added an important new dimension to the diagnosis and treatment of bone loss."

Patient undergoing dual photon absorptiometry of lumbar spine at the University of Kansas Medical Center. Sodium iodide detector (at right) picks up "44 and 100 keV" emissions from gadolinium-153 in shielded source holder positioned beneath the imaging table. (Courtesy of the University of Kansas Medical Center)

Senator John Glenn questioned HCFA about "possible hindrances to the appropriate diagnosis and treatment of osteoporosis."

ACNP President Schuyler V. Hilts, MD, further explained that some disorders affect cortical bone (as found in the distal radius) which is measured by single photon absorptiometry; but the vast majority of conditions affect trabecular bone (as found predominantly in the vertebrae) which is measured by dual photon absorptiometry.

"The trabecular bone loses and gains density far more rapidly and to a far greater degree than the cortical bone," Dr. Hilts continued. "It is clinically important to be able to measure these relatively rapid changes that can occur in the central skeleton as evidenced by the lumbar vertebrae bone density."

The OHTA told *Newsline* that it is willing to review any other information relevant to this assessment. Any readers interested in contributing should address their comments to: National Center for Health Services Research, Office of Health Technology Assessment, Park Bldg., Rm. 3-10, 5600 Fishers La., Rockville, MD 20857. (Although the deadline was set for January, the OHTA said it has a few weeks' flexibility.)

Beyond the medical community, the public is becoming more aware of osteoporosis. *Newsweek* (Sept. 17, 1984) recently reported that diet and exercise could stave off the disorder, while new detection devices can monitor it. *Consumer Reports* (Oct. 1984) has also covered osteoporosis, including a table of 16 calcium-tablet products for the comparison shopper. While both publications printed optimistic news about photon absorptiometry, neither mentioned that the procedures may not be covered by health insurance carriers.

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1. Wahner HW, Dunn WL, Riggs BL: Assessment of bone mineral. *J Nucl Med* 25:1134–1141, 1241–1253, 1984

2. Kimmel PL: Radiologic methods to evaluate bone mineral content. *Ann Intern Med* 100:908–911, 1984

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January 10, 1985

Enrique D. Carter, M.D.
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Park Building, Room 3-10
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Dear Dr. Carter:

The American College of Nuclear Physicians (ACNP) appreciates the opportunity to comment on the Office of Health Technology Assessment (OHTA) activities to assess various bone mineral analysis techniques. We consider bone mineral analysis to be an extremely important and cost effective diagnostic procedure for providing select health care services, particularly for patients with osteoporosis.

Osteoporosis is a common condition affecting as many as 15-20 million persons in the United States. About 1.3 million fractures attributable to osteoporosis occur annually in people aged 45 years and older. The annual cost of osteoporosis in the United States has been estimated at $3.8 billion annually. (NIH Consensus Conference, April, 1984). However, this accounts for only part of the cost to American society and does not reflect the decrease in the quality of life for our older population.

Osteoporosis and the threat of fracture causes a significant alteration in life style in many of our older individuals. Their appearance may be changed by the kyphosis and loss of height attributable to osteoporosis of the vertebral spine. They may refrain from going out in inclement weather and taking part in many other activities, accentuating a reclusive life style, which is counterproductive in terms of their physical and mental well-being. In addition, of those patients who suffer hip fracture, twenty-five percent are dead within a year and over half of those remaining will be institutionalized in a nursing center for long-term care.

Osteoporosis can be detected at its earliest stages by dual-photon absorptiometry of the trabecular bone of the vertebral spine. If we are to postpone or prevent the problems of insidious progressive osteoporosis, early detection and screening by bone mineral analysis of the lumbar spine by dual-photon absorptiometry is critical.

Today's endocrinologist relies heavily on the absolute bone density measurements as provided by dual-photon absorptiometry of the lumbar spine, as well as the patient's individual status as determined by history, physical, dietary history, level of regular physical activity, family history of the disease and several other important factors known to either place an individual at risk for the development of serious osteoporosis. Therefore, an informed risk/benefit decision requires accurate data on each individual patient's bone density. There is ample evidence in the medical literature now which supports the conclusion that combination management of patients with calcium replacement, regular exercise, deletion of drugs which the patient may be taking which interfere with calcium absorption, the effects of cortisone on skeletal density, the long term administration of thiazide diuretics, hormonal replacement or addition (female or male patients), and in serious cases of bone loss, the addition of fluoride (under controlled conditions) can not only halt the progressive loss of bone mineral content, but in many patients, can actually reverse the bone mineral loss and show a demonstrated replacement in strengthening of bone mass by the institution of a total management program.

The disease is a major problem in the rapidly aging population of this country. We now have the techniques to manage it, but that management does not need to be as rigorous in the majority of the population. Thus, we need a way to identify those individuals at highest risk, so that they can be put on the most aggressive therapy. That decision requires the availability of accurate dual-photon absorptiometry measurements of the trabecular bone as evidenced by measurements of the lumbar spine.

The information which follows gives a brief review of the history of non-invasive methods to follow bone density and bone metabolism in osteoporosis and other metabolic bone disorders.

During the past two decades, a variety of non-invasive procedures have been developed in order to gain a better understanding of metabolic bone disorders. These procedures -- photodensitrometry, radiogrammetry, single- and dual-photon absorptiometry, neutron activation analysis, and quantitative computed tomography -- are well-tested and clinically applicable to assess bone mineral. They provide the means to diagnose and monitor bone loss from metabolic-bone disease, to monitor bone loss due to aging, to assess drug effects on bone mineralization, and to assess fracture risk at specific bone sites.

These procedures are non-invasive and therefore minimize the risk to patients. Radiogrammetry and photodensitrometry involve trace amounts of radiation exposure; single-photon absorptiometry involves a 2 to 5 mrad dose to the limb with a negligible body

dose; and dual-photon absorptiometry, directed at the spine, involves a 5 to 15 mrad exposure. The radiation exposures are as low as those received from any diagnostic x-ray or nuclear medicine procedure in use today, and are well within the exposure standards established by the National Council for Radiation Protection and the Nuclear Regulatory Commission.

As practicing nuclear medicine physicians, we feel that it is particularly urgent that dual-photon absorptiometry of the spine be considered an approved technology. Single-photon absorptiometry of the forearm (radius) is already widely accepted, although dual-photon absorptiometry of the spine is far superior to single-photon absorptiometry of the radius in detecting most cases of early osteoporosis. There are many patients in whom both values are helpful in assessing the duration and extent of their disease. For example, although the values at the radius usually change slowly over time and reflect more advanced disease, the values in older patients with significant degenerative spine disease and who may already have collapsed lumbar vertebrae will give a falsely elevated density reading of the spine because the bone that is left has been crushed into a more compact and dense volume. Therefore, each technique has its place in the management of an individual patient.

Dual-photon absorptiometry is used to measure the bone density of the lumbar vertebrae in grams per square centimeter. This is accomplished by quantitating the relative absorption of gamma rays of two different energies from a radioactive source as the scanner passes back and forth over the lumbar spine.

This procedure has added an important new dimension to the diagnosis and treatment of bone loss. There are two kinds of bone in the skeleton: cortical bone, as found in the distal radius, and trabecular bone, as found predominantly in the vertebrae. Some conditions affect the cortical bone, which is measured by single-photon absorptiometry. However, the vast majority of conditions affect the trabecular bone long before their effects are measurable at the radius. The trabecular bone loses and gains density far more rapidly and to a far greater degree than the cortical bone. It is clinically important to be able to measure these relatively rapid changes that can occur in the central skeleton as evidenced by the lumbar vertebrae bone density.

Bone is lost preferentially from the spine in many of the metabolic disorders -- post menopausal osteoporosis, hyperthyroidism, and hypercortisolism -- requiring that bone density of the spine be measured rather than simply the forearm density in these situations. Single-photon absorptiometry has been used over the past 12-15 years to analyze the bone mineral content of the forearm, but these studies do not correlate well with early

bone loss in the lumbar spine. Dual-photon technology allows evaluation of the spine and is an extremely valuable tool in making an early diagnosis of many metabolic disorders -- particularly osteoporosis.

The following statement supports the importance of bone mineral analysis in general and dual-photon absorptiometry in particular:

> "At this time there is no optimal technique available for mass screening for early osteoporosis. Dual-photon absorptiometry of the spine has been used in [the Mayo Clinic] as the method of choice in selected patients for early detection of osteoporosis.
>
> [I]mportant clinically useful information can be obtained from single and from repeated measurements of bone mineral ... Data from single measurements compared with the normal range reflect whether mineral content of the total skeleton, or of a particular portion of it, is normal or low. If low, this could be part of the result of one or more previous insults to the skeleton from which the patient has not completely recovered. In the latter case, there may be no relationship of the osteopenia to the patient's present disease. When the same is expressed in fracture risk, however, a single measurement helps to define the severity of the osteopenia with respect to complications. With this information, it is possible to weigh the benefit-to-risk ratio of a given treatment regimen against the fracture risk of the patient.
>
> Repeated measurements give information on rate of bone loss in the skeleton or portion of it, and allow assessment of the activity of the disease or the effects of a treatment regimen.
>
> Not all this information is available from most any one of the methods described. Particularly with respect to fracture threshold and fracture risk data and estimation of rate of bone loss, the greatest clinical experience is with dual-photon absorptiometry of the spine. Similar data for the hip should be available in the near future." ("Assessment of Bone Mineral Part 2" by Drs. Wahner, Dunn and Riggs of the Mayo Clinic and Foundation, The Journal of Nuclear Medicine, 25:1241-1253, November, 1984, p. 1251).

The diagnosis and treatment of osteoporosis is the clearest example of the importance of dual-photon absorptiometry. The ability to make a diagnosis early in the stage of this disease is extremely important for many reasons, particularly in making the decision to place menopausal patients on continuous estrogen therapy to reduce the rate of bone loss. The risks of estrogen

therapy include endrometrial carcinoma, contribution to high blood pressure, and aggravation of any pre-existing breast malignancy. These risks, balanced against the benefits of the therapy, must always be evaluated. When a less than optimal bone mass in a woman entering menopause is identified by dual-photon absorptiometry, physicians have a clearer clinical basis to make the decision to institute estrogen replacement therapy.

Once the decision is made to institute a treatment regimen, dual-photon absorptiometry allows physicians to determine the effect of the therapy. Until recently, little could be done to monitor bone response when calcium supplantation and estrogen maintenance was employed as preventive therapy for menopausal patients. Simply correcting estrogen deficiency and giving calcium supplementation is not sufficient to prevent osteoporosis in a significant number of patients who also have osteomalacia, idopathic hypercalcuria, or dietary phosphate deficiency. The high precision of bone mineral estimation provided by dual-photon absorptiometry is necessary to adequately monitor response to the complex therapies that may be employed in treating such a multi-faceted disease process.

There are numerous papers in the medical literature addressing single- and dual-photon absorptiometry. The following recent publications (attached) provide an excellent review on the status of bone mineral analysis techniques and their value in the clinical practice of medicine:

- "Radiologic Methods to Evaluate Bone Mineral Content - Position Paper", by the Health and Public Policy Committee, American College of Physicians. Annals of Internal Medicine 100:908-911, 1984.

  This position paper by the American College of Physicians reviews the numerous methods available to evaluate bone mineral content.

- Osteoporosis" Summary of the NIH Consensus Development Conference on Osteoporosis, April 2-4, 1984. JAMA 252:799-802, August 10, 1984.

  The abstract of this summary article speaks to the importance of osteoporosis.

- "Non-Invasive Bone Mineral Measurement" by Drs. Wahner, Dunn and Riggs of the Mayo Clinic and Foundation published in Seminars in Nuclear Medicine 13:282-289, July, 1983.

  This article is a good basic review of the several methods to assess bone mineral content and gives a good discussion of both single- and dual-photon absorptiometry.

- "Differential Changes in Bone Mineral Density of the Appendicular and Axial Skeleton with Aging: Relationship to Spinal Osteoporosis". This is a combined paper by the Mayo Clinic Group and the Group at the University of Wisconsin. Published in the Journal of Clinical Investigation pp. 328-335, February, 1981.

  This paper points out the value of combined measurements of bone density in the axial and appendicular skeleton, and served as the basis for providing normal ranges for the Lunar Radiation Equipment currently on the market.

- "Bone Mineral Content of the Radius: Good Correlations with Physico-Chemical Determinations in Iliac Crest Trabecular Bone of Normal and Osteoporotic Subjects", Metabolism 30:57-62, January, 1981.

  This paper points out the excellent correlation with bone mineral content, single-photon absorptiometry determination at the radius and iliac crest biopsy.

- "Steroid-Induced Fractures and Bone Loss in Patients with Asthma", by Adinoff and Hollister, New England Journal of Medicine 309:265-268, 1983.

  This paper points out the importance of the availability of dual-photon absorptiometry measurements of trabecular bone to detect early bone loss in patients who are receiving high doses of corticosteroids.

- "Bone Mineral Content of Amenorrheic and Eumenorrheic Athletes" by Drinkwater et al. New England Journal of Medicine 311:277-281, 1984.

  This excellent study evaluated a sub-set of individuals known to become osteoporotic, that is young female athletes in serious training for long-distance running who may become amenorrheic.

- "Non-Invasive Bone Measurement". A book chapter reviewing a variety of methods to determine bone density by Dr. Richard B. Mazess. This review was published in Skeletal Research. Vol. 2, Chapter 9, pp. 277-343, Academic Press, 1983.

  This is an excellent, in-depth review of the theory and practice of measuring bone density in patients.

- "Assessment of Bone Mineral, Part 1 and 2" by Drs. Wahner, Dunn and Riggs of the Mayo Clinic and Foundation published

in The Journal of Nuclear Medicine 24:1134-1141, October, 1984, and 25:1241-1253, November, 1984.

A study of the different techniques currently available to study bone minerals.

In our view, the effectiveness of bone mineral analysis generally and single- and dual-photon absorptiometry in particular has been clearly established. Further, dual-photon analysis procedures are already recognized as clinically effective by many Blue Cross/Blue Shield plans including Maryland, Pennsylvania, Florida, California, Minnesota and Wisconsin. The College strongly urges the Public Health Service to recommend this technique in order that more patients can benefit from the early detection and treatment of bone diseases.

We will be pleased to answer any questions or provide additional information as appropriate to assist in your assessment activities. Thank you for the opportunity to contribute to your review.

Sincerely,

AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

Schuyler V. Hilts
President

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December 21, 1984

Enrique D. Carter, M.D.
Director, Office of Health
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Public Health Service
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Rockville, MD 20857

Dear Dr. Carter:

The Society of Nuclear Medicine is pleased to respond to your request for information concerning bone mineral density studies. The Society of Nuclear Medicine is the preeminant scientific professional organization in the field of nuclear medicine. Its 10,000 plus members reflect all of the medical, scientific and technical personnel active in providing nuclear medicine service in the USA, Canada and throughout the world.

The attached document was prepared by Heinz W. Wahner, M.D. of the Mayo Clinic, a respected expert on this issue. His considered conclusion is that bone mineral studies should become part of the work-up of patients with osteoporosis and that dual photon absorbiometry (DPA) is the technique of choice.

Reimbursement decisions should be consistant with this conclusion.

Sincerely,

Henry L. Ernstthal
Executive Director

HLE:lsc

Enc.

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ASSESSMENT OF BONE MINERAL DENSITY STUDIES FOR BONE MINERAL MEASUREMENTS

Numerous methods for the assessment of bone mineral have been available to the physician in the last three decades. While these techniques have advanced our knowledge of bone disease in general they had little impact on the management of the individual patient. In the last few years two methods, dual photon absorptiometry and quantitative computed tomography, have been developed with a great potential for use in the general clinical practice. Of these two, dual photon absorptiometry is at this time the method of choice. Together with single photon absorptiometry these two methods are all that is needed for routine clinical evaluation of the skeleton with respect to bone mineral. This review will therefore center on a summary on dual photon absorptiometry.

Dual photon absorptiometry for the evaluation of bone mineral was developed by Reed (1) and Roos (2) in the early seventies, was adopted for total body calcium and lumbar spine measurements by Wilson and Madson (3) and co-workers in the laboratory of R. Mazess in the mid-seventies and used for measurements on the hip by Dunn, Wahner, Riggs in 1980 (4). The method has been tested extensively on phantoms and patients in northern Europe and the USA (Krolner, Christiansen) and its clinical usefulness and the limitations have been well documented. The method has been reviewed by specialists in Bone Diseases and recommendations on the use of this procedure are available from an expert panel from the American College of Physicians (5) and the Osteoporosis Concensus Conference (NIH). Because these recommendations are rather general, a more specific review of the method itself and the basis for its application in the management of patients with bone disease is attempted in the following. Several review articles are available on the subject (6-10). Several manufacturers (Novo, Lunar Radiation) now produce instruments of proven quality and two additional manufacturers have just entered their product to the market (Norland, Nuclear Data). Because of the use of a radioactive source, personnel in a Nuclear Medicine or Radiology Department would be most familiar with this type of equipment. Alternative methods for bone mineral measurements in the spine are available using computed x-ray tomography (CT) or limited neutron activation analysis. Both methods have not had the clinical trials that DPA has and are rather expensive and not generally available. (10). Other methods performed on appendicular bone, such as radiogrammetry, single photon absorptiometry or density indices are of little value in Osteoporosis, but may have some application in renal bone disease. For review of these techniques see references (6-9).

The following abbreviations will be used in the text:

DPA=Dual Photon Absorptiometry; SPA=Single Photon Absorptiometry; BM=Bone mineral (g/cm^2) in DPA; BMC=Bone Mineral content (g/cm) in SPA.

Clinical Applications: Measurements of bone mineral are performed on patients for one or more of the following reasons:

1. To measure cortical appendicular (SPA) and trabecular axial (DPA) bone mass. The result is then compared with a sex and age specific normal range. From this is derived a statement whether bone mineral is normal or abnormally low. The result helps define the impact of a given disease on the skeleton at the time of examination.

2. To relate the measured bone mineral result to the fracture threshold for a given skeletal site and place the result above or below this threshold.

3. To define the fracture risk at a specific site by comparing the measured bone mineral results with fracture risk estimate and fracture mineral (spine, hip, radius) and fracture prevalence. These estimate are presently being developed and have been presented in abstract form. (Melton, Wahner, Riggs) This fracture risk estimate may be helpful to define the risk/benefit ratio of a given treatment regimen.

4. To estimate the rate of bone loss by repeated measurements (3-6 months apart) and compare this to the known rates of loss from age and sex specific normal ranges. The resulting information indicates whether bone loss is accelerated or normal for age and sex.

5. To define specific types of bone loss by comparing bone loss in axial (DPA) and appendicular (SPA) skeletal sites. This is of value in NaF treatment where cortical bone may be lost but trabecular bone gained.

6. To monitor patients on drug treatment in order to assess response, identify the nonresponders so that they can be started on alternative treatment regimens and determine the time at which futher treatment is not necessary because the patient has reached the maximal achievable effect.

Method: The description of the method is quoted from H.W.Wahner et al. Noninvasive Bone Mineral Measurements, Seminars in Nuclear Medicine 13, 282-289, 1984.

"The method is based on measurements of radiation transmission of two separate photon energies through a medium that consists primarily of two different materials, bone and soft tissue. The absorptiometer consists of a rectilinear scanner frame, a 1.5 Ci(55.5 GBq) ^{153}Gd source, and a NaI(Tl) detector. The Gadolinium-153 energy spectrum has photoelectric peaks in Na(Tl) at approximately 44 keV and 100 keV (Europium K x-rays, 42, 48 keV, and gamma rays 97, 103 keV).

The following equations describe the absorption of each photon energy in a medium composed of bone and soft tissue.

$$I^{44}\,x, y = I_0^{44} \exp\,[-(\mu/\rho)_{st}^{44} \cdot M_{st} - (\mu/\rho)_{bm}^{44} \cdot M_{bm}] \quad (1)$$

$$I^{100}\,x, y = I_0^{100} \exp\,[-(\mu/\rho)_{st}^{100} \cdot M_{st} - (\mu/\rho)_{bm}^{100} \cdot M_{bm}] \quad (2)$$

$I^{44}\,x, y$ and $I^{100}\,x, y$ refer to the transmitted radiation beam intensity at a point x, y for 44 keV and 100 keV photon energies, respectively. I_0^{44} and I_0^{100} are the unattenuated photon intensities. The mass attenuation coefficients of soft tissue and bone mineral at energy A are represented by $(\mu/\rho)_{st}^{A}$ and $(\mu/\rho)_{bm}^{A}$, respectively. The mass per unit area (g/cm^2) of tissue and of bone mineral is indicated by M_{st} and M_{bm}. The following solution for bone mineral is derived from equations 1 and 2.

$$M_{bm} = \frac{RST\,(\ln I^{100}\,x, y/I_0^{100}) - (\ln I^{44}\,x, y/I_0^{44})}{(\mu/\rho)_{bm}^{44} - RST\,(\mu/\rho)_{bm}^{100}} \quad (3)$$

where $RST = (\mu/\rho)_{st}^{44}/(\mu/\rho)_{st}^{100}$. (For explanation see subsequent text.)

In the measuremnt of bone mineral, a rectilinear scan of the region of interest is performed with the source detector assembly, and a point-by-point determination of bone mineral is made. The total bone mass is determined by summing the individual M_{bm} point values. The RST value is averaged over all the extraosseous area that is scanned, and the average RST is used to calculated M_{bm}.

The actual absorption coefficients for soft tissue do not need to be determined. The RST is calculated from the measured radiation intensities as follows.

$$\left.\begin{aligned} I^{ce}(x,y) &= I_0^{ce}\exp\left[-(\mu/\rho)_m^{ce}\cdot M_m\right] \\ I^{ce'}(x,y) &= I_0^{ce'}\exp\left[-(\mu/\rho)_m^{ce'}\cdot M_m\right] \end{aligned}\right\} \text{ In tissue only}$$

$$\ln(I_0^{ce}/I^{ce}(x,y)) = (\mu/\rho)_m^{ce}\cdot M_m$$

$$\ln(I_0^{ce'}/I^{ce'}(x,y)) = (\mu/\rho)_m^{ce'}\cdot M_m$$

$$(\mu/\rho)_m^{ce}/(\mu/\rho)_m^{ce'} = \ln(I_0^{ce}/I^{ce}(x,y))/\ln(I_0^{ce'}/I^{ce'}(x,y)) = RST$$

In order to calculate RST accurately, the regions that are occupied by bone must be located. The bone surface area and edge limits are defined by an edge detection routine that is based on the change in the magnitude of M_{bm} at the bone tissue interface. Experiments with water, fat and ashed bone in phantoms demonstrate that the RST averaging procedure corrects for the presence of varying amounts of fat.

The output is a character or intensity plot of bone mineral For the spine the region of L1 through L4 is calculated. For the hip, bone mineral is calculated at the site of the femoral neck, trochanter, and shaft."

Accuracy: Accuracy for measurements of bone mineral in spine and hip with DPA devices has been evaluated by many investigators. The results are expressed as coefficient of correlation (CC) between the measured units, (computer units) and the true bone mineral.

Different laboratories have reported a high accuracy with CC at about 0.999, over the range of bone mineral which can be expected in clinical measurements. Accuracy studies were done on phantoms simulating bone such as aqueous solutions of dipotassium-hydrogen phosphate, on Aluminum tubes, on dried or ashed bones without bone marrow, on excised untreated lumbar vertebrae, and on cadavers prior to removal of the spine.

Past studies with single energy absorptiometry of the radius have shown fat content of bone and surrounding tissue to be a major factor in measurement errors. Changes in bone marrow fat i.e. an increase in fat with advancing age in vertebrae has been of major concern. This problem was evaluated in a multicenter study. (Wahner et al) (submitted for publication) The results are summarized as follows: (Abstract)

"Dual-photon absorptiometry with ^{153}Gd was used to measure the mineral content of lumbar vetebrae in cadavers (n = 9), intact excised vertebrae

(n = 24), and dry, marrow-free vertebrae (n = 39). The error introduced by the surrounding soft tissue was 3%; the error in determing mineral mass or density in excised vertebrae was about 5%. The effect of progressive removal of fat (ether-acetone extraction), studied in three vertebrae, was minimal; a 10% change in fat caused a 0.3% change in measured bone mineral content. A similar effect was observed in an annular bone phantom in which the central water-filled area was replaced with margarine. The correlation coefficient between results of ^{153}Gd and ^{125}I (single-photon) absorptiometry on 24 femoral necks was 0.99; the predictive error was 3.7%. Dual photon absorptiometry accurately indicates bone mass and bone density and is only slightly affected by either surrounding tissue or bone arrow composition."

High accuracy is needed when the results are used to place the patient inside or outside the normal range, i.e. for the detection of bone loss.

Precision: Precision, i.e. reproducibility has been tested in vitro and in vivo in long-term and short term experiments. The results are expressed in coefficient of variation (CV). Schaadt and Bohr (6) have reported values obtained on normal young volunteers for lumbar spine, femoral neck and femoral shaft over periods varying from 1 week to 19 months. The average coefficient of variation was found to be 1.18% in lumbar spine (range 0.41-0.77%) 0.93% (range 0.15-2.07%) in femoral neck and 0.88% (range 0.000-2.30%) in femoral shaft. In another study long term precision in vivo of bone mineral in the lumbar spine averaged 2% in normal premenopausal woman, 2.7% in normal postmenopausal women, and 3.5% in women with osteoporosis (11, 12). The same authors claim just above 1% (CV) for long term reproducbility (2 ½ years) on cylindrical bone equivalent standards. Values at or below 2.5% for the lumbar spine have been reported for older subjects and subjects with osteoporosis from several investigators. (Wahner, Riggs, Dunn; Krolner, Christiansen, Roos, Mazess).

High reproducibility is important for longitudinal studies such as follow-up studies in patients on drug regimen, designed to prevent bone loss or to increase bone mass. Since the normal bone loss is about 1% per year, stringent demands have to be made on the technique to detect 3-5% loss per year, which is significant for medial decision making.

Measuring Procedure: For measuring bone mineral by DPA, the patient is positioned suspine on the scanning table. The legs are slightly elevated to reduce the lumbar lordosis. The scanning probe and source assembly on a C-arm is then positioned over the mid-abdomen by the level of T12 (just below the xiphoid process) using a Laser beam as centering device. Scanning is then initiated. The 4 mm beam (8-13 mm in other instruments) of Gamma rays (44, 100 keV) then scans with a speed of about 1-2 mm/sec across the spine. The increment between scan lines is about 0.5 to 1.0 cm. The instrument is manually stopped when the iliac crest is reached (L5). By direct interaction with the computer, the scanned area is displayed, the area of interest, usually L2-L4 is identified and the results are obtained in mass per unit anterior spine area (gm/cm^2). The time for one procedure is 30-45 minutes.

Quality Control: The instruments are standardized with ashed bones or bone equivalent solutions in specially designed phantoms. Daily quality control phantoms are supplied and need to be used.

Radiation Dose: Radiation dose has been calculated by different investigators. While it depends somewhat on beam size, source geometry and strength, scanning speed and distance from the source (all these factors vary slightly with different instruments) radiation dose from one scan to the ovaries and abdomen is in the neighborhood of 20-50 mrads. Dunn et al (4) have determined the radiation dose by thermoluminescent dosimetry (TLD) on phantoms and patients to be between 5 and 15 mrads (0.05 - 0.15 mGy) (peak skin dose at beam entrance).

Bone Mineral Loss and Age: The following is quoted from an article by B.L. Riggs, H. W. Wahner, et al: Differential Change in Bone Mineral Density of the Appendicular and Axial Skeleton with Aging. Relationship to Spinal Osteoporosis. J. Clin Invest 67: 328-335, 1981.

"Abstract: Patterns of bone loss in the axial and the appendicular skeleton were studied in 187 normal volunteers (105 women and 82 men; age range, 20-89 yr) and in 76 women and 9 men with vertebral fractures due to osteoporosis. Bone mineral density was measured in vivo at the lumbar spine (predominantly trabeulcar bone) by dual photon absorptiometry and at the midradius (95% cortical bone) and distal radius (75% cortical and 25% trabecular bone) by single photon absorptiometry. In normal women, bone diminution from the vertebrae began in young adulthood and was linear. In the appendicular skeleton, bone diminution did not occur until age 50 yr. was acclerated from ages 51 to 65 yr. and then decelerated somewhat after age 65 yr. Overall bone diminution throughout life was 47% for the vertebrae, 30% for the midradius, and 39% for the distal radius. In normal men, vertebral and appendicular bone diminution with aging was minimal or insignificant. Mean bone mineral density was lower in patients with osteoporosis than in age- and sex-matched normal subjects at all three scanning sites, although spinal measurements discriminated best; however, there was considerable overlap. By age 65 yr. half of the normal women (and by age 85 yr. virtually all of them) had vertebral bone mineral density values below the 90th percentile of women with vertebral fractures and, thus, might be considered to have asymptomatic osteoporosis. For men, the degree of overlap was less. The data suggest that disproportionate loss of trabecular bone from the axial skeleton is a distinguishing characteristic of spinal osteoporosis.

Bone Mineral and Fracture: The clinical relevance of bone mineral measurements rests on the ability of the technique to predict bone fracture,since morbidity or mortality originates from fractures and treatment is designed to prevent or reduce the occurence of fractures. The relationship between fracture risk and bone mineral mass therefore has to be examined. Decreased strength of bone and increasing susceptibility to fracture are related to the quantity of bone mineral in both trabecular and cortical bone, but they are not identical. Geometric changes in compact bone with aging, predominant loss of either cortical or trabecular bone, the occurrence of microfractures and cortical-porosis all can alter the relationship between breaking strength and bone mineral. Despite these restrictions measurements of bone mineral have been used successfully to predict breaking strength of excised bones in the laboratory and have been used successfully to define fracture risk in epidemiological studies. This information is just now becoming available.

As yet unpublished studies (Melton, Wahner, Riggs) show a high relationship between bone mineral of the spine and hip, and fracture preva-

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lence in spine and hip respectively in a study of the general population. A fracture threshold has been established which is identical for male and female below which there is a significant and rapidly increasing risk of fracture. A value below which all patients have spinal compression fractures has been defined.

There is no strict cut-off between normal and abnormal subjects with regard to Osteoporosis. The epidemiological model employed with hypertension is a much more appropriate one. As the risk of stroke increases with the blood pressure, the risk of fracture increases with the decrease in bone mineral.

In summary, the relationship between bone mineral and bone fracture has been established by physical measurements on excised bones by epidemiological studies on fracture prevalence and by clinical observation on patients. Of all the methods presently used in the evaluation of metabolic bone disease bone mineral measurements at the site of expected fractures are most useful to predict fractures.

Metabolic Bone Disease: Schaadt and Bohr (6) studied 30 Prednisone treated women with dual and single absorptiometry of spine and hip respectively and reported the greatest diminution of bone mineral in the spine which consists of predominantly trabecular bone. There was less bone loss in the hip which consists of a mixture of trabecular and cortical bone and the smallest bone loss in the femoral shaft, which is pedominantly cortical bone. Similar results were obtained by Seeman, Wahner et al (13) who studied 100 patients with various types of endocrine dysfunction with SPA of the radius and DPA of the spine. Bone mineral in each endocrine dissorder deviated at least in one site from sex-specific age regression of 187 normal subjects from the same laboratory. For patients with primary hyperparathyroidism, hypercortisolism and hyperthyroidism this deviation was negative (suggesting bone loss) whereas for patients with secondary hyperparathyroidism due to chronic renal failure, acromegaly and post surgical hypoparathyroidism it was positive (suggesting bone gain). When all six states of endocrine dysfunction were compared concomitantly by multivariate analysis of variance, the profile of the changes in bone mineral differed significantly ($p < 0.001$), indicating a non-uniform response of bone to the various hormonal alterations. When values of bone mineral for the 3 different sites (distal radius, mid radius, lumbar spine) were compared, the mid-radius and distal radius did not differ significantly. Both radius measurements however differed significantly from the lumbar spine. This study demonstrates convincingly that bone mineral of the axial skeleton cannot be reliably predicted from measurements made in the appendicular skeleton, because the effects on endoccrine dysfunction on bone mineral are complex and both site and disease specific.

Therapy of Osteoporosis: Therapeutic agents for osteoporosis should not only prevent further bone loss but should also increase bone mass to a level which exceeds the fracture threshold. For this to be achieved bone formation must be substanstially greater than bone resorption. Most currently available therapeutic agents, -sex steroids, calcium, calcitonin - act by reducing bone resorption rather then by increasing bone formation. In a typical case of osteoporosis when treated with these drugs, at first, resorption falls to a level below that of formation. This condition, however, is short lived, because

of a secondary decrease of bone formation. After about 6 months, a new steady state is reached wherein the level of bone formation approximates or is less than that of bone resorption. Despite of this the effectiveness of these drugs, is that they showed down bone resorption. This generally results in a decrease in the occurrence rate of new fractures. However, with these drugs the skeleton remains prone to fractures, and the bone mineral remains below the fracture threshold. Among experimental agents only the synthetic 1-34 fragment of parathyroid hormone has been shown to be capable of stimulating bone formation. The use of this agent, however, is fraught with theoretical and practical difficulties. Only Sodium fluoride results in an increase in skeletal mass or bone mineral.

New bone formed under the stimulus of Sodium fluoride may exhibit various degrees of osteosclerosis osteoporosis, osteomalacia and architectural disorganization. Of these manifestations only osteosclerosis increases bone strength. For the therapeutic use of sodium fluoride therefore conditions must be carefully chosen to maximize the development of osteosclerosis and minimize undesirable manifestations. The results from iliac bone biopsies have shown an increase in trabecuar bone volume with NaF. Hanson and Roos with x-ray dual absorptiomery showed that bone mineral increased in the spine by an average of 1% per month. This dramatic increase in the trabecular bone of the spine is not accompanied, however, by a similar increase in cortical bone of the appendicular skeleton and there may even be a loss of bone mineral in cortical bone (Ringe, Dambacker, Riggs) These observations raise the possibility that fluoride therapy may protect against fractures of the vertebral bodies but may not protect the proximal femur which is predominantly cortical bone and may even increase the risk of fracture in this bone. NaF is at present still not released for general use and can only be used with an IND.

This illustrates that in drug therapy of osteoporosis monitoring of trabecular and cortical bone sites and of one or more of the actual fracture sites should be done to assess the effectiveness in the individual patient, evaluate the peak effectiveness, the time of declining effectiveness and make judgements when side effects of the treatment increase perhaps only temporarily the risk of fracture. Monitoring during treatment and selection for treatment cannot be done routinely with bone biospy. Chemical tests on blood and radiographs on bone are too insensitivie. At this time only bone mineral measurements at different sites of the skeleton (hip, spine, radius) can routinely be employed under clinical conditions for this purpose.

Seasonal Variation: DPA of the spine has been used to show seasonal variations in spinal BM in Scandinavian woman (14) Such seasonal variations have however not been observed in Minnesota women. (Wahner et al, 1983) in a longitudinal study covering a 2 year period.

Bed Rest: Bone loss following bed rest was found most pronounced in the spine (I5), but was reversible. Similar changes have been noted in cortical bone of the extremities with inactivity of a limb such as with casts.

Physical Exercise: Physical exercise as prophylaxis against involutional bone loss was evaluated in a controlled trial by Krolner, (16). There was a significant increase in spinal bone mineral following controlled exercise.

Total Body: The DPA-method has been used to measure total body bone mineral by scanning the entire skeleton. A good correlation with total body calcium by neutron activation analysis was demonstrated. A commercially available instrument exists for this purpose. This application of DPA is at this time however of limited clinical usefulness since total body bone mineral can be predicted with high accuracy from measurements on cortical bone sites. (total skeleton is 80% cortical bone, 20% trabecular bone). The clinical needs appear to be more for independent cortical and trabecular bone measurements and measurements of specific sites which are prone to fracture than for total body calcium measurements.

Summary:

1. Dual photon absorptiometry of the spine is a reliable method to diagnose and follow patients with Osteoporosis. The information given is not available with any other procedure with comparable accuracy, precision, acceptability to the patient and for this relatively low cost. Several manufacturers are producing instruments which meet the standards defined for research instruments and allow accurate and reproducible measurements under routine laboratory conditions. Information on bone mineral is needed to identify patients in need for treatmment for Osteoporosis and then to monitor these patients for treatment effectiveness, to exclude patients resistant to a specific treatment regimen and to identify the end of the effectiveness of the treatment.

2. The method has potential applications in monitoring exercise programs in their effectiveness to prevent bone loss in the spine and hip. This is just now under investigation. The use of supervised exercise programs to increase bone mineral is a very interesting aspect in management of patients, with long periods of bed rest,but needs further clinical investigation before being recommended for general clinical use.

3. The use of DPA of the spine or hip in patients with metabolic bone disease, patients on long-term steroid use, anticoagulants or other drugs known to reduce bone mass may be of importance in certain cases, but bone mineral measurements do not necessarily have to be a part of the rotuine work-up.

4. In certain cases of liver and gastrointestinal diseases associated with bone loss DPA of the spine may also be helpful to identify bone loss prior to fractures.

5. In patients with renal disease bone loss is not uniform in the skeleton and results from different skeletal sites are contradictory. While in rare cases BM measurements may be of importance, we do not feel that routine BM measurements should be a part of the routine work-up.

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POSITION PAPERS

Radiologic Methods to Evaluate Bone Mineral Content

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THE DIAGNOSIS AND MANAGEMENT of metabolic bone diseases such as osteoporosis, osteomalacia, and renal osteodystrophy are facilitated by the ability to determine accurately the nature and degree of changes in bone mineral content. Changes caused by metabolic bone disorders may progress slowly, and short-term changes may be subtle.

The axial skeleton is composed largely of trabecular bone, and the appendicular skeleton is mostly cortical. Most metabolic bone diseases affect trabecular (cancellous) bone to a greater extent than cortical bone, because of the higher turnover rate of the former. In many metabolic bone diseases, fractures tend to occur at sites that contain relatively large amounts of trabecular bone (1, 2). Therefore, changes in the amount of trabecular bone content may be more sensitive indicators of early metabolic disorders than changes in cortical bone. Measurements of bone mineral content in the appendicular skeleton have been shown to correlate poorly with measurements in the axial skeleton (3-6). There may be some advantages to determining bone mineral content at the site of pathological bone loss and fracture, or at a site of high trabecular bone content.

Osteoporosis, a decrease in bone mass (as compared to age- and sex-matched controls) and secondary mechanical failure of the skeleton, is the commonest metabolic disorder of bone. Osteoporosis may be drug induced, idiopathic, secondary to ovarian failure (postmenopausal), or a result of aging (senile). In patients with osteoporosis, vertebral body collapse and fractures of the proximal femur and distal forearm commonly occur with minimal trauma (2). Osteoporosis usually is diagnosed only after the occurrence of a fracture. Decreased bone mineral content is an important, but not the only, determinant of fracture incidence (7). Measurement of bone mineral content may help differentiate patients prone to osteoporosis from age-, sex-, and race-matched patients without this tendency.

Simple bone radiographs are not sufficient to diagnose early bone loss, because losses of up to 40% of bone mass may occur before a noticeable change is detected (2). Recently, noninvasive procedures have been developed that permit improved sensitivity in measurement of bone mineral content.

The major use of noninvasive means of quantifying bone mineral content are in those osteopenic conditions where there is a quantitative decrease in bone mass without a qualitative defect. Hence, the methods for evaluating osteopenia (bone loss) are more appropriate in the osteoporotic conditions, and less useful in conditions such as osteomalacia, hyperparathyroidism, and renal osteodystrophy.

Definitions

Radiogrammetry measures the thickness of the cortex of metacarpal or other tubular bones on standard anteroposterior roentgenograms of the hand. From such measurements, various derived indices of the cortical bone volume are calculated. The technique is widely available and simple, requiring only the ability to take reproducible bone roentgenograms and make fine caliber measurements. Radiogrammetric measures may be compared to a large normal population, and are usually precise and reproducible. Small changes in endosteal and periosteal cortical resorption may be found by serial measurements. However, radiogrammetry does not reflect reliably the absolute bone mineral content, and does not measure intracortical bone mineral porosity. Therefore, radiogrammetry only provides information on relative change in bone volume. The technique has mainly been applied to the appendicular skeleton.

Photodensitometry uses the bone mineral image on standard radiographic film as an indicator of photon absorption by bone, and therefore indirectly measures bone mineral content. The degree of film whitening is measured by a photodensitometer (or occasionally by a chemical assay of the amount of silver on the exposed film). Calibration of each film is accomplished by simultaneous exposure of a reference aluminum alloy wedge that has a similar rate of x-ray absorption as bone.

Single-energy photon absorptiometry measures mineral content in the appendicular skeleton and usually is done on the radius. A monoenergetic photon source, such as iodine-125, is coupled with a sodium iodide scintillation counter detector. The difference in photon absorption between bone and soft tissue allows calculation of the total bone mineral content found in the scan path, which is inversely related to the measured transmission

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count rate. Bone mineral content is expressed as bone mineral per square centimeter scanned.

Dual-energy photon absorptiometry is a modification of the single-energy technique using a radioisotope that emits photons at two different energy levels. Dual photon absorption measurement eliminates the need for a constant soft tissue thickness across a scan path, allowing use in previously inaccessible areas such as the spine. The signal produced is independent of variations in soft tissue components scanned (8). The influence of irregular overlying fat distribution may be corrected during scanning (8). Both absorptiometry methods measure the total integrated mineral in the path of the beam.

Computed tomography also may be used to measure bone mineral content. A mineral reference standard (such as K_2HPO_4 solution) is required for calibration as is a scout view for localization. Either the single- or dual-energy technique may be used. Data from scans of small volumes (3 to 4 cm^3) of the midportion of the vertebral bodies are quantified and averaged and used in conjunction with calibration data to calculate mineral equivalents, expressed in milligrams of K_2HPO_4 per cubic centimeter. Total, cortical, or trabecular bone mineral density can be calculated.

Neutron activation analysis uses a source of high energy neutrons to activate body calcium-48 to calcium-49. The subsequent decay back to calcium-48 can be measured with a gamma radiation counter to provide a measurement of total body calcium. Because greater than 98% of total body calcium is skeletal, this technique assesses total bone calcium content. Modifications of this technique allow the assessment of regional calcium stores.

Table 1. Comparison of Techniques Used to Measure Bone Mineral Content

Technique	Precision*	Reliability†	Radiation Exposure	
			Local Tissue	Gonads
	← % →			
Radiogrammetry			Up to 100 mrad	Negligible
Photodensitometry	1-4	6	Up to 100 mrad	Negligible
Photon absorptiometry				
Single energy	3-5	1-4	2-5 mrad	Negligible
Dual energy	1-3	4-6	5-15 mrad	2 mrad
Computed tomography				
Single energy	1-3	8‡	200-250 mrad	Variable; may be as low as 10 mrad
Dual energy	3-5	2-4‡		
Neutron activation analysis	2-3	6	300-5000 mrad	Not available

* Precision is a measure of the reproducibility of the test on repeated determinations (that is, the percentage figures that appear in the precision column show the degree of variation in a test result when the test is done several times on the same specimen).

† Reliability provides an index of the correlation of the methods with reference standards (that is, the percentage figures that appear in the reliability column show the degree of difference between the bone mineral content as estimated by the test compared to the bone mineral content calculated by the reference standard, ash weights).

‡ Reliability figures may be decreased in the elderly.

Safety

All of these techniques are noninvasive, but do involve patient exposure to radiation (Table 1). Radiogrammetry and photodensitometry involve minimal radiation exposure, with negligible bone marrow or gonadal radiation. Single-energy photon absorptiometry involves a 2 to 5 mrad dose to the limb (usually forearm). The body dose is negligible, because there is virtually no scatter (9). The radiation dose for dual-energy photon absorptiometry is directed at the spine, and involves a 5 to 15 mrad exposure (8, 10). The total dose to the ovaries is less than 2 mrad, and the bone marrow dose is less than 0.2 mrad (8). Routine spinal roentgenograms for localization may add to the total radiation exposure. The radiation exposure from computed tomographic studies of vertebral trabecular bone is significantly greater and less defined. Radiation doses of 200 to 250 mrad localized to a 10-cm region of the upper abdomen (one tenth the amount involved in a usual lumbar computed tomographic study) have been used effectively (11). The resulting gonadal dose is less than 10 mrad. In addition, if anatomic considerations are unimportant, a computed tomographic study for bone mineral content may be done using about half of the above dose (12). However, some institutions have reported surface radiation doses up to ten times greater for such studies (13). Total body neutron activation analysis requires higher radiation doses, generally on the order of 300 to 5000 mrad. Partial body neutron activation analysis requires proportionally smaller radiation doses. In comparison, a routine chest radiograph involves an exposure of 20 to 40 mrad and a lumbar spine series entails one of 600 mrad, with a large percentage of gonadal radiation. The background surface radiation exposure per person in Philadelphia is 120 mrad/yr (Hale J. Personal communication).

Efficacy

Because of the heterogeneous nature of the skeleton and the differences in technique, each method has its unique advantages and limitations. The precision, reliability, and radiation exposure of each method is shown in Table 1.

Photodensitometry has technical problems relating to radiographic technique and methods of film processing that limit its use. However, recent advances such as radiographic absorptiometric techniques may have reduced these problems (14). Single-energy photon absorptiometry is dependent on careful positioning of the bone site examined during sequential testing. In addition, the technique requires a uniform soft tissue thickness surrounding the bone, rendering measurement of the spine difficult. Dual-energy photon absorption does not provide absolute measurement of bone mineral content, because the amount of bone scanned differs with the size of the skeleton and must be subsequently normalized. The reliability of single-energy computed tomography is variable and depends on the fatty tissue of the trabecular bone marrow. Dual-energy computed tomography allows more reliable determination of bone mineral content independent of fat and water variation, but at the expense of reduced precision.

Radiogrammetry, photodensitometry, and single-energy absorptiometry are used to measure the mineral content of the appendicular skeleton, but are not useful for the axial skeleton. Therefore, these methods of quantifying bone mineral content may be of limited clinical use in assessing those metabolic bone diseases that usually involve areas of proportionally greater trabecular bone content, such as the spine.

Both dual photon absorptiometry and computed tomography have been used to determine rates of bone mineral loss of the spine in normal and osteoporotic persons (6, 11, 15). Differences in calculated rates of bone loss between the two methods may depend on differences in the character of populations studied or on technical variations. Dual photon absorptiometry measures attenuation of a photon beam through the body, and therefore provides an integrated sum of cortical and trabecular bone. Attenuation by extraosseous calcification in osteophytes or vascular structures may contribute to inaccuracy in measurement (2, 16). In addition, vertebral compression with callous formation and deformity may contribute to the inaccuracy of such integrated measurements in osteoporotic persons.

Computed tomography may be used to measure cancellous bone, cortical bone, or an integrated sum of both (17). This use may be a theoretical advantage if the measurement of purely trabecular bone provides a better method of quantifying change in a metabolic bone disease than the measurement of cortical bone alone. The method can identify the absolute mineral content of a specific volume of bone. Computed tomographic measurements may be falsely lowered 20% to 25% (16, 18) in elderly, osteoporotic persons because marrow fat concentration increases with age. Using age-related regression analysis for calculating mineral content may reduce inaccuracies somewhat (16). Dual-energy techniques can reduce the magnitude of this error caused by fatty composition, but at the expense of an increased radiation dose.

Findings from both computed tomography and dual photon absorptiometry are reasonably precise and correlate with measured ash weights of isolated bone (8, 19-21). Both methods have been used to follow changes in axial skeletal bone mineral content over time (6, 11, 15). Photon absorptiometric methods tend to correlate better with results from neutron activation analysis, the "gold standard" for total skeletal calcium measurement (22). The distribution of calcium within bone, however, may be more important than its total magnitude.

Cost

Single-energy photon absorptiometry costs from $35 to $120; dual-energy evaluation costs from $150 to $300. Photodensitometric techniques may cost up to $65. Computed tomographic bone densitometry costs $95 to $350 per scan.

Conclusions

Several radiologic techniques are available to assess bone mineral content. However, all methods of bone mineral content measurement may result in significant overlap between diseased and normal populations. Improvements in present techniques to measure bone mineral content are likely to become more helpful in identifying individual patients, such as those with asymptomatic osteoporosis before development of clinical evidence of the disease (such as fracture). The ultimate benefit of early diagnosis of a metabolic bone disease will depend on the clear establishment of safe and effective treatments. Currently there is evidence that prophylaxis is effective in retarding the development of postmenopausal osteoporosis (11, 23) and that treatment is effective for established metabolic bone disease such as osteomalacia and renal osteodystrophy. Further clinical trials of efficacy are necessary and ongoing. Measurements of bone mineral content have been helpful in separating populations with normal and subnormal bone mineral content (6, 15) and have been useful in following rates of change in bone mineral content that occur spontaneously or after treatment (11, 15). Measurements of bone mineral content have greater use in following the course of a disease process, monitoring drug complications (such as progression of bone mineral loss in patients on steroid therapy), or assessing the effect of therapeutic intervention than in establishing the diagnosis of a specific metabolic bone disease.

Newer radiologic techniques permit the measurement of spinal mineral content and are likely to be increasingly preferable to plain radiographs of the spine. Single-energy photon absorptiometry is inexpensive, but may not be applicable to the spine. Dual photon absorptiometry can be used to quantify changes in bone mineral content in patients who have metabolic bone disease or who are undergoing treatment that alters bone mineral content. Currently, computed tomography has the advantage of quantifying changes in the trabecular portion of the axial skeleton.

Neither dual photon absorptiometry nor computed tomographic techniques can accurately predict the tendency to fracture. Both procedures are expensive. With technical advances, lower radiation exposure, and a decrease in cost, computed tomography may become generally applicable to the evaluation of metabolic bone diseases. If a test of bone mineral content is needed in the evaluation of patients with metabolic bone disease, dual photon absorptiometry may be preferable at this time, because of its lower radiation dosage and cost. Local expertise and availability, however, may be important determinants of use. The relative value of these two techniques has not at present been completely determined.

ACKNOWLEDGMENTS: The Clinical Efficacy Assessment Project (CEAP) of the American College of Physicians is designed to evaluate and inform College members and others about the safety and efficacy of diagnostic and therapeutic modalities. Evaluation of technologies begins with a notice in the *Annals of Internal Medicine* and the *ACP Observer* inviting comments. Appropriate members of the Council of Medical Societies and the Council of Subspecialty Societies as well as other experts are asked to review technologies. The CEAP statements thus represent a synthesis of the literature and expert opinion and are intended to reflect the current state-of-the-art knowledge concerning a technology. Statements may be reconsidered as new information becomes available.

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Jan. 1985

Reimbursement for Bone Densitometry in Osteoporosis

Current evaluations of non-invasive and invasive measurements in osteoporosis by insurers have chiefly focused on the utility of such measurements in predicting fractures. Experts in bone disease, however, in conformity with medical tradition, view the disease process as distinct from its signs and symptoms and therefore assess the utility of such measurements differently. The various measurements of bone are useful clinically for two purposes (a) to assess the degree and extent of previous and ongoing bone loss with regard to fracture risk and (b) to evaluate the metabolic state of bone or calcium metabolism.

BONE METABOLISM

There is consensus that a bone deficit, whether due to an insufficient bone mass at maturity, an accelerated bone loss, or a combination of these, is the principal factor in subsequent fracture or at least establishes significant fracture risk. It also must be recognized that sequential bone measurements can be used to assess bone activity or responsiveness to therapy. For example precise measurements (1% reproducibility) of total body calcium can now be made using dual-photon absorptiometry or by neutron activation. Sequential measurements allow calcium balance to be determined over longer intervals than could ever be achieved economically in a metabolic ward. High precision non-invasive measurements of long bones can be done by several methods; these correlate highly with total body calcium (r >

0.90). Serial measurements of long bones and of the total skeleton have been shown to be indicative of calcium balance. Thus precise (1-2% error) measurements can be useful clinically even should they not correlate highly with fracture. There are obviously many metabolic measurements of value in osteoporosis (serum GLA protein, histomorphometry, calcium absorption, urinary hydroxyproline, Urine calcium/creatinine, etc.) which do not correlate with fracture. Serial changes in these reflect changes of bone metabolism which have important clinical meaning. It should be pointed out, however, that the changes seen in serial bone measurements are often associated with changes of fracture risk even though the magnitude of the bone measurement need not be highly predictive. One example is the precise absorptiometric measurements made by NASA in bedrest studies and in astronauts; the losses seen in bedrest and space flight reflected high calcium losses. Another example is the stabilization of bone mass observed in the radius and metacarpal after treatment with estrogens; this has been associated with a pronounced reduction in fracture. Untreated patients lose bone and fracture significantly more than treated. In this case bone measurements are useful even though a radius or metacarpal value does not perfectly predict fracture risk in the spine or hip (where drug effects are more pronounced). Still the physician could use stabilization of radius or metacarpal values in serial measurements as one indication of efficacy. An alternative clinical use might be in monitoring patients going through periods of potential high bone loss (ovariectomy, menopause,

intestinal bypass, corticosteroids). Higher than acceptable loss rates (1-2% annually) would indicate the need for therapeutic intervention.

It is well-recognized that the trabecular bone of the axial skeleton is about 8-10 times more metabolically active than the compact bone of the peripheral skeleton. As a consequence the influence of various agents influencing bone can be seen far more readily in an area such as the spine than in the long bones. This has been conclusively demonstrated over the past decade with a number of agents causing bone loss (for example, corticosteroids) as well as with therapeutic agents (for example, fluoride). Consequently axial bone is the key area for examination of clinical changes.

FRACTURE RISK

Virtually all bone measurements, including semi-quantitative grading of radiographs, have been shown to be associated with fracture incidence or prevalence in epidemiological studies. A strong inference has been made that this association reflects the predictive value of the measurements on the assumption that (a) any particular bone measurement is not an unrelated concomitant of fracture (for example related only as an aging concomitant) and (b) that certain bone measurements, particularly those at common freacture sites, such as the spine, proximal femur and distal radius, directly indicate the bone strength. Experimental studies have documented the validity of these assumptions. For example fractures occur in young and middle-age patients at almost exactly the same low bone levels at which they occur,

albeit more commonly, in elderly patients. Secondly, bone mass or density at common fracture sites accounts from 80 to 95% of the variance in strength and resistance to fracture. The question therefore is not if these measurements are predictive but how well they predict fracture risk.

It is obvious that no bone measurement can predict the occurrence of a fracture just as a blood pressure level cannot predict the timing of a stroke or a cholesterol level predict when a coronary problem will occur in an individual. Fracture risk can be assessed by either large-scale epidemiologic studies in which prevalence or incidence is related to the bone measure or by more difficult prospective studies. Only one prospective study has been done using bone measurement methods (Khari, et al., 1976). This showed that at normal radius bone levels (using single-photon absorptiometry) there was little or no risk of fracture while at lower levels the risk increased greatly (four-fold). The small sample size, and limited time-period of observation, however, prevented a detailed delineation of relative risk. Numerous prevalence studies have shown a similar association of increased fracture with lower bone levels. There do remain questions concerning the relative clinical utility of various measurements based on sensitivity and specificity. Without going into great detail on measurement methods, it is clear that some approaches are preferable to others. First, semi-quantitative indices have been of marginal utility. Second, any measurement (so long as it is precise and accurate) at a site away from the actual site of clinical import will tend to be non-specific. For example radius shaft measurements (by single-

photon absorptiometry, or neutron activation, or photodensitometry) will all predict fracture risk in general but will misdiagnose a large class (30-40%) of crush fracture patients. It sould be noted that this patient grouping includes some people with preferential spinal osteopenia; as a group they lie 1.5 to 2.5 SD below age-matched controls in spinal density but only 1 to 1.5 SD below normal in compact bonew. There is also some evidence that patients with fractures of the proximal femur have preferential osteopenia in the Ward's Triangle area of the femur but not necessarily elsewhere in the femur or the skeleton (Vose and Hurxthal, 1964). Third, measurements as a fracture site (spine, proximal femoral, distal radius) will usually provide the best indication of fracture risk at that site. It is now clear that fractures (and bone levels) at these sites are somewhat independent; a bone measurement highly predictive at one site, for example the spine or distal radius, will not necessarily predict femoral fracture. The lowest levels of bone "density" at a fracture site are associated with a relative risk of fracture that is 50 to 100 times the risk at normal levels. This may be compared with the increased cardiovascular risk associated with the tenfold increase in coronary risk associated with an increase of cholesterol level. from 140 mg/dl to over 340 mg/dl.

Although there is a well-defined association between bone mass, or density, and fracture risk the clinical import depends upon the differential in fracture risk within the population under consideration. Measurements would be of little value if

the relative risk were uniform. Within the older population at risk of fracture (>50 years) bone levels are reduced on the average 2 SD below the levels seen in young adults. Osteoporotic patients range from 3 to 5 SD below young normal. The relative fracture risk at the latter level is at least 10 times greater than at 2 SD below normal (J. Melton, 1984, reported at Am. Soc. Bone Mineral Research). Thus bone measurements are of value even within this restricted age population.

REIMBURSEMENT

With regard to reimbursement for specific bone measurement procedures, it appears inappropriate for insurers to make decisions among alternative technologies all of which have validity. An extension of this policy would have insurers reimbursing for particular brands of instrumentation and not for others since the differences among manufacturers appear as great in some instances as the differences among procedures. The differences in clinical results obtained with different approaches actually have more to do with the site of measurement than the procedure. A CT scan on the radius shaft is no more valid than an absorptiometric scan (single- or dual-photon) at the same site.

By way of example, insurers, in general, do not specify the type of bone scanning agent (HEDP, MDP, HMDP) for which reimbursement is acceptable but merely specify "bone scan, local area" or "bone scan, total body". It would be appropriate to likewise specify levels of reimbursement as well as frequency of measurement for "bone densitometry" with subcategories of

"peripheral skeleton", "axial skeleton", and "total skeleton". The decision among alternative densitometric methods is best made by the physician based on costs, availability, radiation dose and technical factors. Nearly all of the technologies available today do in fact measure bone with physically acceptable levels of precision and accuracy but the technologies differ in their ability to measure different skeletal sites.

It is very reasonable for insurers to develop criteria for clinical assessment in order to prevent expenditures for costly but marginally useful technology. It is clear that measurements of the peripheral skeleton (mostly done at present using single-photon absorptiometry) have been effective in the past decade in the identification and therapy of osteoporosis. New high precision approaches using several different methods at more trabecular areas (distal radius) have further enhanced clinical utility of peripheral measurements. Measurements of the spine, proximal femur and even the total skeleton using newer methods (computed tomography, dual-photon absorptiometry) offer the prospect for early diagnosis and for effective treatment of bone disease. It has already been shown that these methods of examining fracture sites and assessing metabolic activity are clinically more useful than the measurements on the peripheral skeleton. Such technology must not be hindered from clinical implementation. At the same time it is appropriate, and consistent with fiscal prudence to provide a limit on reimbursement levels for such procedures and a limit on the frequency of measurements.

Single-photon absorptiometry and most methods of measuring

the peripheral skeleton are no more complex than a chest film. The costs for machinery are no greater and the interpretation is less complex. Consequently the reimbursement level could be comparable. It is unlikely that significant changes would be seen in one year in the peripheral skeleton of an osteoporotic patient or in a normal subject, even during the immediate postmenopausal period, so the maximum frequency could be done annually. Dual-photon or computed tomographic measurements of the spine or proximal femur take from 3-8 times longer to perform, involve more costly instruments and supplies, and require greater technical skills and interpretation. Given this, and the greater clinical utility of axial measurements, a reimbursement level 2-3 times more than that for a peripheral measurement (or chest film) is reasonable. Since changes with therapy can be evident in as little as six months the maximal frequency can be set twice annually. Total skeletal determinations are the most time consuming and costly and could have a reimbursement limit double that of axial bone determination. It should be recognized that the overall costs of even several total body determinations would be less than the costs of tests for calcium absorption and calcium balance. The cost of such non-invasive tests also is generally less than that of a full radiograhic series. Even a single diagnostic test on the axial skeleton is about half the annual cost of the cheapest current preventative/therapeutic agent for osteoporosis and about 20% of the annual cost of several other proposed agents. Setting limits on reimbursement for these tests will prevent medical

profiteering and will limit implementation of bone measurement technology to those centers with an adequate patient base to reasonably support it.

It must be noted that bone densitometry for other bone diseases, particularly in children, will require more frequent monitoring. Bone changes with corticosteroids, immobilization, renal osteodystrophy, ovariectomy and hyperparathyroidism for example are large and rapid. Determinations twice annually are justified in adults and four times annually in children.

Attached is a list of articles bearing on (a) the relationship of bone measurements to bone strength and fractures and (b) the use of bone measurements to assess skeletal metabolism and the response to therapy.

Authored by R.B. Mazess, University of Wisconsin, for an ad hoc panel of experts on osteoporosis.

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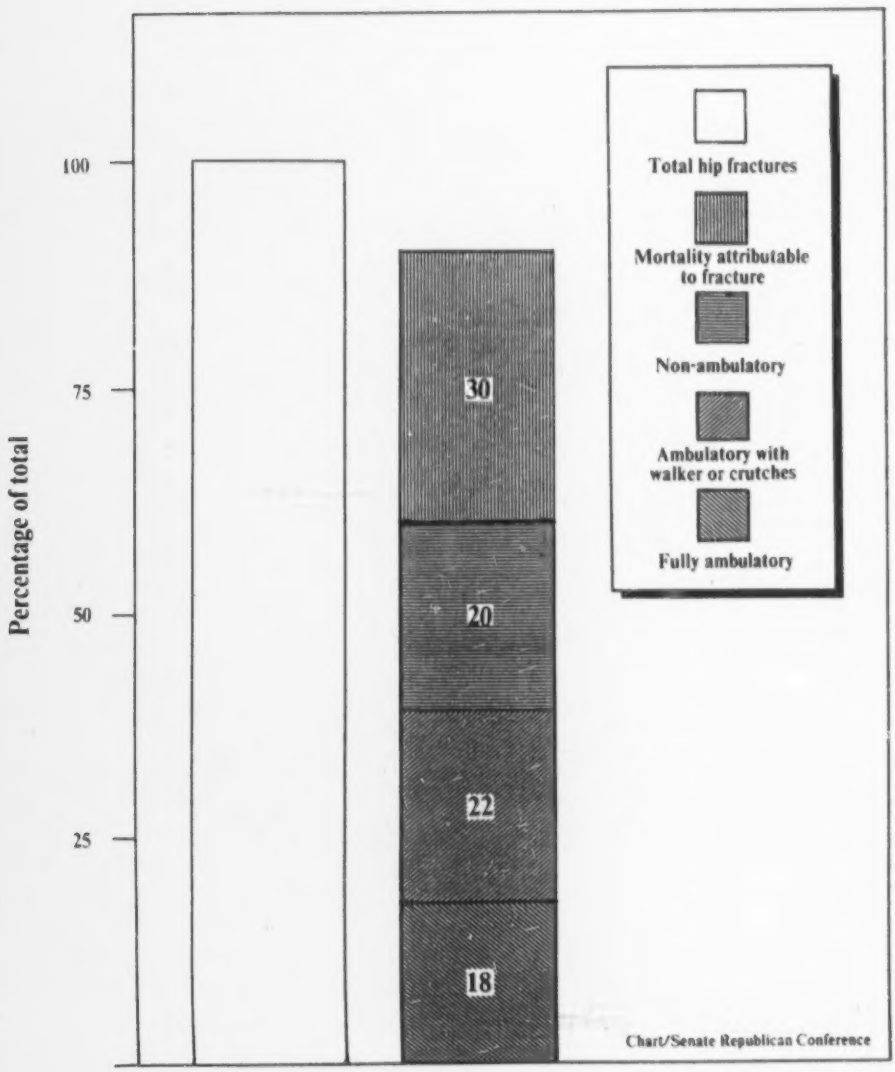
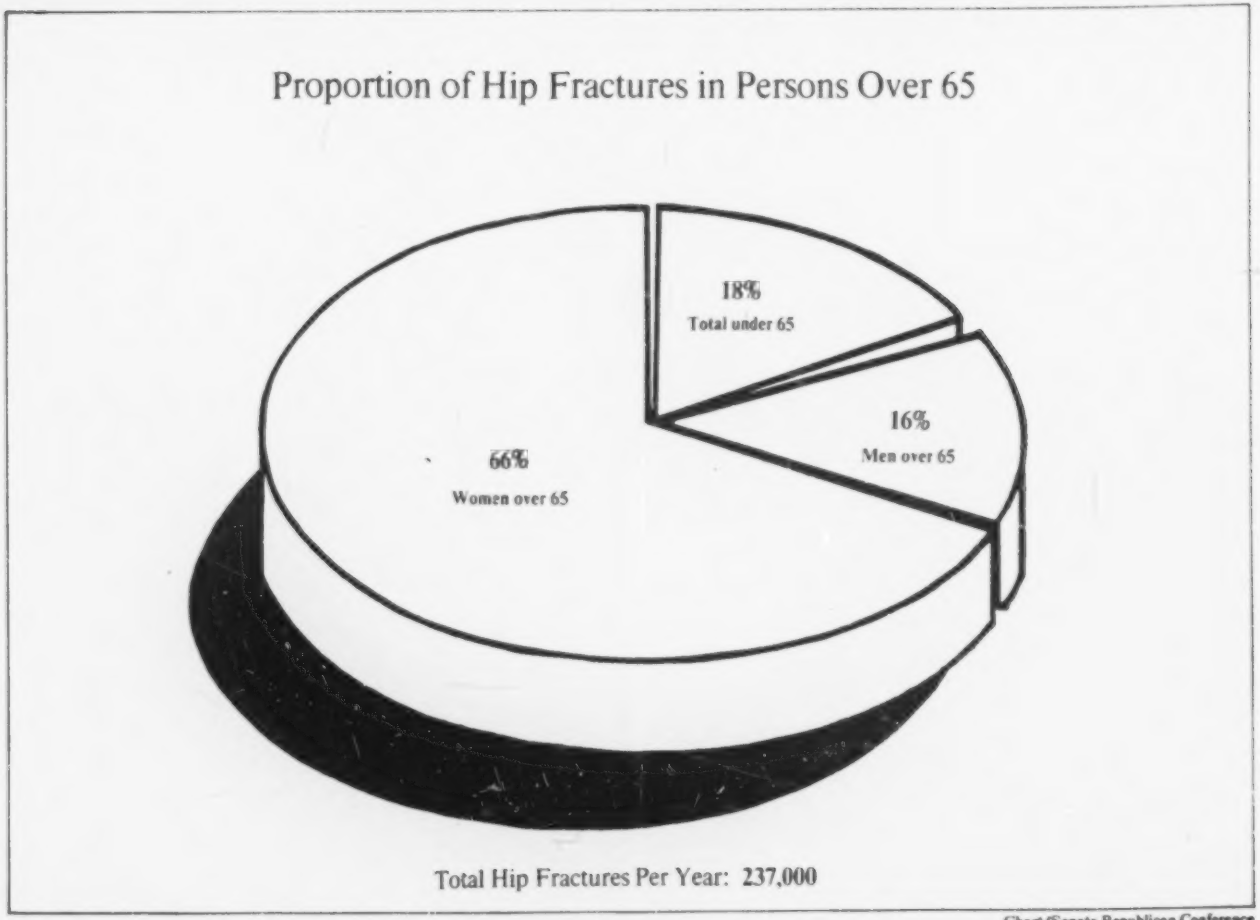
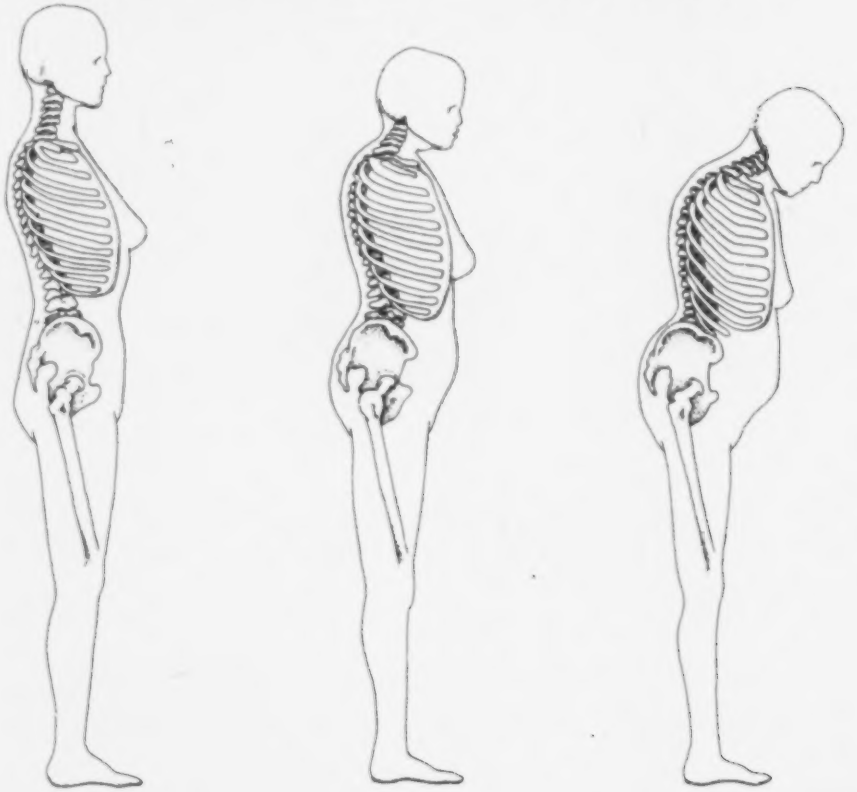
Clinical Outcomes
One Year After Hip Fracture



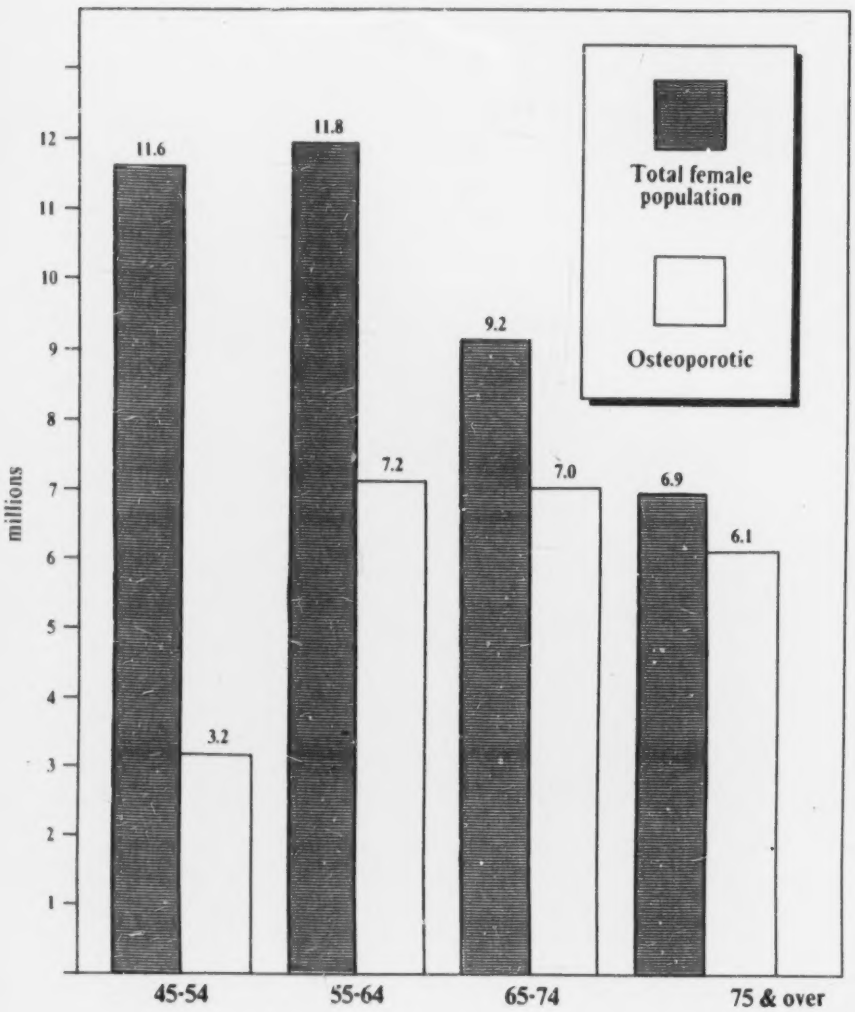

Proportion of Hip Fractures in Persons Over 65
18%
Total under 65
16%
Men over 65
66%
Women over 65
Total Hip Fractures Per Year: 237,000
Chart/Senate Republican Conference

Osteoporosis often causes the collapse of spinal vertebrae. This can lead to what is known as "Dowager's Hump".



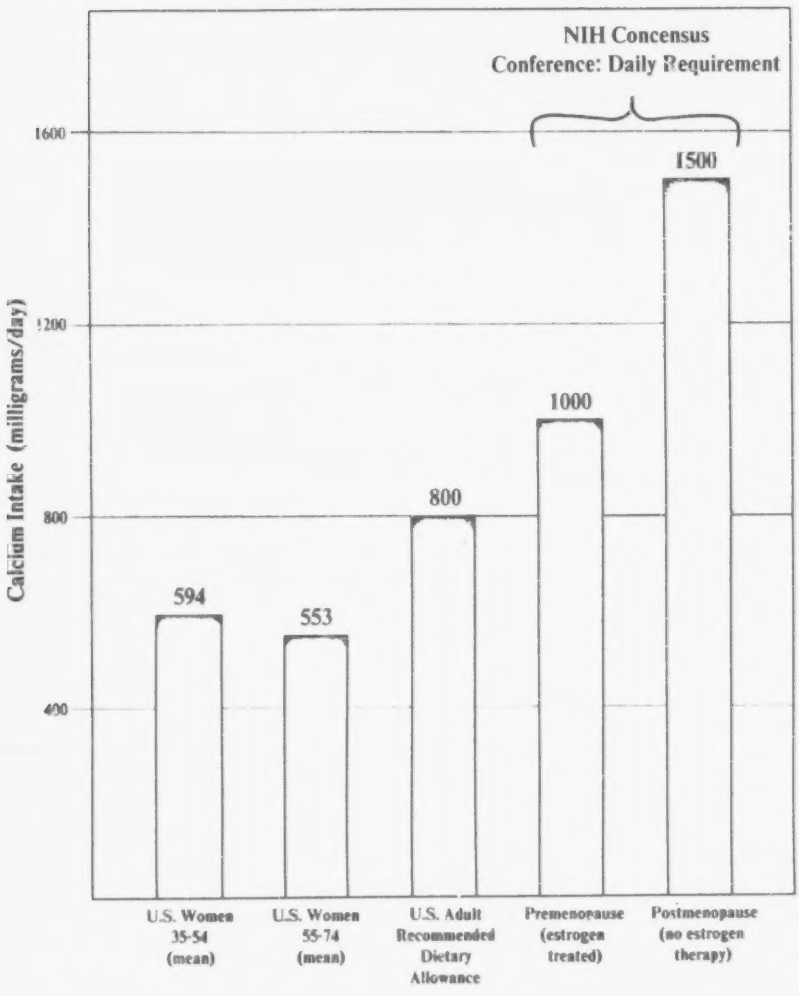
Chart/Senate Republican Conference

Prevalence of Osteoporosis Among American Women, Age 45 and Over

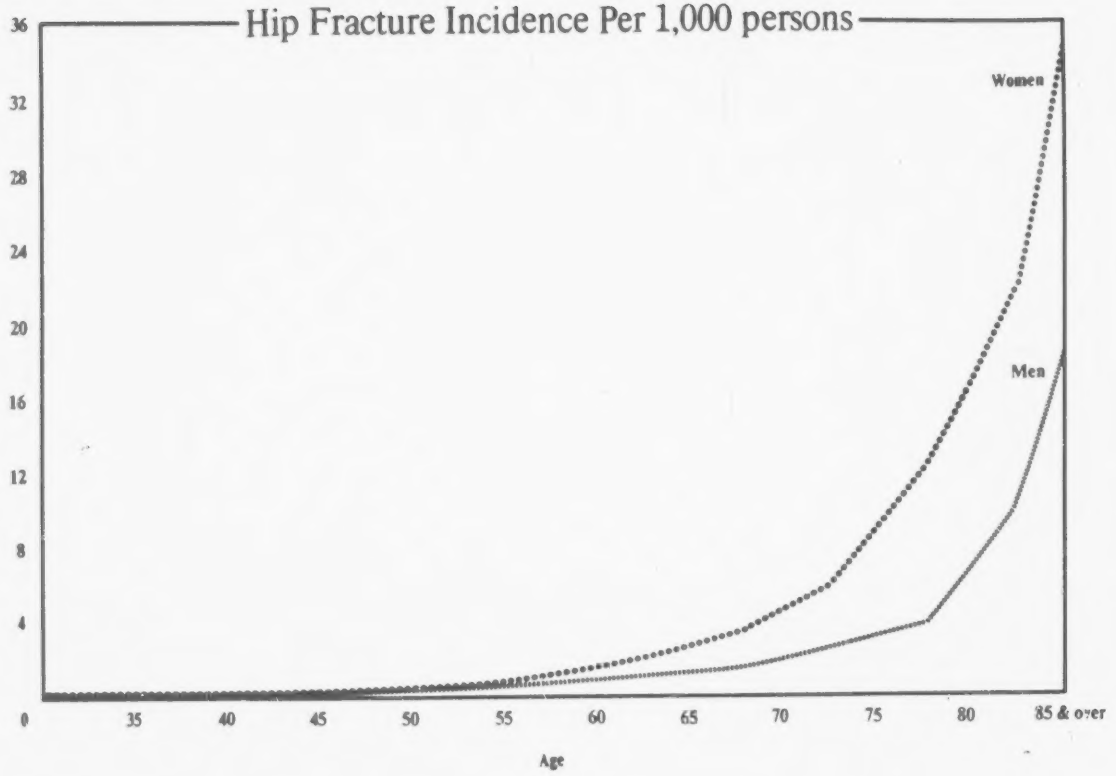


Chart/Senate Republican Conference

Recommended and Actual Calcium Intake, U.S.



Chart/Senate Republican Conference



Chart/Senate Republican Conference

[Whereupon, at 12:25, the subcommittee adjourned, subject to the call of the Chair.]

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